Department of Health and Human Services
Food and Drugs Administration
Center for Drug Evaluation and Research
Office of New Drugs
Office of Drug Evaluation IV
Division of Nonprescription Drug Products

MEDICAL OFFICER'S MEMO

Subject:	Trolamine Salicylate Clinical Safety Review for Sunscreen Monograph
Date completed review:	November 28, 2017
Reviewer:	s22 [redacted]
Team Leader:	s22 [redacted]
Signatory Authority:	s22 [redacted]

I. Executive Summary:

In 1978, the Sunscreen Advisory Panel at the Food and Drug Administration (FDA) determined that up to 12% trolamine salicylate (TS) sunscreens were safe and effective to use on humans as over-the-counter sunscreen drug products.[1] In an effort to support TS's future rulemaking and clinical safety, scientific literature search was conducted.

Based upon literature review, this reviewer concludes that the available clinical safety data does not support continued inclusion of TS sunscreens in the final monograph for over-the-counter (OTC) sunscreen drug products under the listed conditions.

The information available, described below, includes a case report of bleeding and a drug-drug interaction with topical application of TS which can lead to serious medical complications including death. Additionally, there is a potential for salicylism (a toxic condition produced by the excessive intake of salicylic acid or salicylates) from application of salicylic acid lotions as described in this review. The issues of bleeding, salicylism, and drug-drug interaction are serious concerns because salicylates are widely used by consumers for cardiovascular and analgesic indications. Therefore, the widespread use of TS sunscreens would likely result in a significant increase of mentioned complications, which may be severe.

[1] Federal Register (May 21, 1999); 64(98):27666-93.

II. Recommendations:

If consideration is given toward continued inclusion of TS in the monograph, a full battery of testing would be required, including: 1) dermal safety studies including cumulative irritation and sensitization; 2) photosafety studies; 3) maximal use studies (MUsT); 4) carcinogenicity studies; and 5) reproductive and developmental studies.

However, there are serious concerns regarding salicylism with use over the body surface area and frequency required for conduct of a MUsT for a sunscreen indication which would preclude approval of human clinical safety testing. Such studies in humans would be unethical. The literature reports are serious enough to warrant exclusion of TS from OTC Final Monograph for sunscreen drug products.

III. Introduction:

This is a clinical safety review of sunscreen drug products for OTC human use containing trolamine salicylate.

Salicylates were discovered in late 1700's from bark of a willow tree. Salicylates have been widely used as analgesics, anti-pyretic, and anti-inflammatory agents over the years. Aspirin is an acetylated salicylate that is available without a prescription like other salicylates [ibuprofen and naproxen (nonacetylated salicylates)]. Aspirin, unlike other salicylates such as ibuprofen and naproxen, acts as an acetylation agent that irreversibly inhibits platelet's cyclooxygenase (COX) which in turn leads to reduced prostaglandins and thromboxane A_2 production thereby inhibiting platelet aggregation. Reduced platelet aggregation leads to reduced cardiovascular events including myocardial infarction, stent thrombosis, and transient ischemic attacks. Common adverse reactions associated with salicylates include dyspepsia, nausea, vomiting, diarrhea, abdominal pain, rash, hyperuricemia, dizziness, and ecchymosis as well as gastric and duodenal ulcerations leading to gastrointestinal bleeding. At high doses, acute salicylate toxicity (salicylism) may occur. Early symptoms of salicylism include tinnitus, vertigo, nausea, vomiting, and diarrhea; subsequent symptoms portending a more severe intoxication include altered mental status (ranging from agitation to lethargy), hyperpyrexia, noncardiac pulmonary edema, and coma.[2] Rarely, salicylates use is associated with severe asthma exacerbation, Reye's syndrome, and angioedema.[3, 4]

Topically applied salicylates, including trolamine salicylate, are known to be systemically absorbed.[5,6] Therefore, systemic adverse effects related to salicylates may occur. In addition, because consumers may not recognize that a topical product contains salicylates, drug-drug interactions may occur with oral non-steroidal anti-inflammatory (NSAID) drugs as well as antithrombotics, such as warfarin.

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[2] https://www.uptodate.com/contents/salicylate-aspirin-poisoning-in-adults?source=search_result&search=salicylate%20toxicity&selectedTitle=1~109#H4
[3] https://www.uptodate.com/contents/aspirin-drug-information?source=see_link#F137057
[4] https://www.uptodate.com/contents/aspirin-mechanism-of-action-major-toxicities-and-use-in-rheumatic-diseases?source=search_result&search=salicylate%20toxicity&selectedTitle=3~109#H13
[5] Rose FA and Wiemer DR. Platelet coagulopathy secondary to topical salicylate use. Ann Plast Surg. 1983. 11(4):340-3.
[6] Madan RK and Levitt J. A review of toxicity from topical salicylic acid preparations. J Am Acad Dermatol. 2014. 70(4):788-92.

IV. Safety Data Review:

To assess the safety of TS, the scientific literature was searched for published articles on the clinical safety of trolamine salicylate. Specifically, the scientific literature was searched for all published articles on trolamine salicylate (triethanolamine salicylate OR trolamine salicylate) AND (safe OR safety OR "side effect" OR "side effects" OR adverse OR "adverse effects" [subheading] OR toxic* OR hazard*) using PUBMED, EMBASE, Web of Science, and EBSCOhost. Literature search produced about 76 articles. Due to limited availability of time to complete this review, source of information reported in the articles that were reviewed was not verified. Three articles summarized below pertain to this review:

- In 1983, Rose and Wiemer[7] reported a case of coagulopathy due to topical trolamine salicylate. A 69-year-old woman underwent perioral chemical peel and a cervicofacial rhytidectomy followed by quadrilateral blepharoplasty. Patient was advised to discontinue aspirin two weeks preceding her surgery, and she complied. Patient's laboratory tests, which included clotting profile, hematocrit and platelet screen, were normal before surgery. Patient's intraoperative course lasting three hours was unremarkable. However, four hours later, patient was bleeding profusely from all surfaces that were operated and had massive bilateral hematomas. Patient returned to the operating room and had lost at least 900 ml of blood. Platelet counts were mildly decreased when rechecked. Hematological consultation was obtained. Patient received 10 units of platelets, 10 units of cryoprecipitate, 4 units of fresh-frozen plasma, and 6 units of red blood cells transfusion. At the end of re-exploration, patient was massively edematous and received 1 g of Solu-Medrol®. Due to significant facial edema, wounds could not be approximated and patient underwent secondary healing process. Postoperatively, patient admitted to using copious amounts of trolamine salicylate cream (Aspercreme®) on her knees for painful arthritis. Unfortunately, this information was not obtained during preoperative evaluation because patient did not think that Aspercreme® was a medication, but merely an emollient.

- In 1990, Littleton[8] reported a case involving a 68-year-old man treated with warfarin therapy for atrial fibrillation and stroke prevention. Patient's prothrombin time was stable and in the therapeutic range of 1.3 to 1.5 times the control for several months. However, on a routine follow up, patient's prothrombin time was 2.5 times the control value without bleeding or bruising. Upon questioning, the patient admitted that he was liberally applying topical trolamine salicylate to his neck and shoulders on several occasions due to pain. Patient was advised to stop this practice and his prothrombin time returned to 1.3 times the control.

Reviewer's comments:

[7] Rose FA and Wiemer DR. Platelet coagulopathy secondary to topical salicylate use. Ann Plast Surg. 1983. 11(4):340-3.
[8] Littleton F. Warfarin and topical salicylates. JAMA 1990. 263(21):2888.

These two published articles outline the potential dangers of trolamine salicylate cream even though it was used for treating osteoarthritis pain. One patient did not consider TS cream as a medication and therefore did not report its use to her physicians before surgery.

If trolamine salicylate were used as a sunscreen, a significantly higher amount of the drug product and potentially frequent application would be required to maintain protection against ultraviolet (UV) radiation. This could significantly increase the likelihood of systemic effect and drug-drug interactions.

- Although not directly related to trolamine salicylate, in 2014, Madan and Levitt[9] published a review article outlining toxicity from topical salicylic acid preparations. The authors noted that topical salicylic acid, which is often used in dermatologic conditions because of its keratolytic, bacteriostatic, fungicidal, and photoprotective properties, was related to numerous toxicity and death cases. The authors searched PubMed database from 1966 to 2014 which revealed toxicity directly linked to topically applied salicylic acid in 13 cases of psoriasis, 8 cases of ichthyosis, 2 cases of tinea imbricata, 1 case of erythroderma, and 1 case of seborrheic dermatitis. Toxicity often appeared within a few days of use. The most severe cases, leading to coma and death, occurred in patients with psoriasis. The age at which toxicity occurred was evenly distributed between adults and children. Toxicity with application of as little as 1% to 2% salicylic acid has been reported in neonates. Per authors, in every case salicylic acid was applied to a large body surface area. The authors also reviewed an article which reported that before 1964, there were 13 deaths due to salicylic acid toxicity from topical applications of salicylic acid. Of those 13 deaths, 3 patients had psoriasis, 5 scabies, 3 dermatitis, 1 lupus vulgaris, and 1 had congenital ichthyosiform erythroderma.

  Additionally, the authors estimated that 60% of salicylic acid is absorbed with intact skin. Per authors, systemic effects of topical salicylic acid are minimal when it is applied to intact skin in low to moderate doses. Conversely, with a break in the stratum corneum, measurable levels of salicylic acid can be found in the body even after application of low concentrations in hydrophilic ointment. The authors reviewed articles where cutaneous microdialysis was used to show that salicylic acid with petrolatum or ethanol applied to tape-stripped skin is absorbed 150 times more than when applied to intact skin. The authors presented an estimate of salicylic acid exposure based on a theoretical scenario. If a patient applies salicylic acid lotion to 70% of the body surface area [approximately most of the arms, legs, and trunk (very likely required for sunscreens)], a single application is roughly 16 g. If a patient applies 16 g of a 6% salicylic acid lotion (the Monograph allows up to 12% trolamine salicylate concentration in sunscreens), it would contain 1 g of salicylic acid. If 60% of 1 g is absorbed, the maximal plasma level would be 0.6 g. Based on the volume of distribution, plasma concentration of salicylic acid would equate to 35 mg/dL. The level at which salicylic acid toxicity begins is at 35 mg/dL. The half-life of salicylic acid can range from 2 to 12 hours depending on the dose. Even if 16 g of lotion is

[9] Madan RK and Levitt J. A review of toxicity from topical salicylic acid preparations. J Am Acad Dermatol. 2014. 70(4):788-92.

applied twice a day, salicylic acid could accumulate in the body and levels could even become high enough to cause death.

***Reviewer's comments**:*
Although the article by Madan and Levitt does not relate to trolamine salicylate directly, it does provide general information about salicylic acid lotions used for dermatological conditions. It outlines the potential danger of trolamine salicylate sunscreen. If trolamine salicylate is allowed on the market as a sunscreen, a significantly higher amount of this drug product will need to be applied to the skin to protect the skin from damage by UV radiation of the sun than that used as an external analgesic. Additionally, trolamine salicylate sunscreen will require more frequent application to maintain its protection from UV radiation, which could significantly increase the likelihood of systemic drug effects and drug-drug interactions.

From: s22
To: s22 ; COMB Systems
Cc: s22
Subject: RE: Implement a "Fail validation" rule for Trolamine salicylate [SEC=OFFICIAL]
Date: Wednesday, 31 July 2024 2:18:41 PM
Attachments: image001.png

No worries. Thanks, s22

s22
Assistant Director – Business Improvement and Support Section
Complementary and OTC Medicines Branch

Medicine Regulation Division | Health Products Regulation Group
Australian Government Department of Health and Aged Care
T s22 | E s22 @health.gov.au

Location: Gulgana 1 South
PO Box 9848, Canberra ACT 2601, Australia

I acknowledge the First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community.
I pay my respects to them and their cultures, and to all Elders both past and present.

From: s22 @Health.gov.au>
Sent: Wednesday, July 31, 2024 2:18 PM
To: COMB Systems <COMB.SYSTEMS@HEALTH.GOV.AU>
Cc: s22 @Health.gov.au>; s22 s22 @health.gov.au>; s22 @health.gov.au>
Subject: RE: Implement a "Fail validation" rule for Trolamine salicylate [SEC=OFFICIAL]

Thanks s22, and yes that's correct, due to safety concerns.

s22

From: COMB Systems <COMB.SYSTEMS@HEALTH.GOV.AU>
Sent: Wednesday, July 31, 2024 2:13 PM
To: s22 @Health.gov.au>; COMB Systems <COMB.SYSTEMS@HEALTH.GOV.AU>
Cc: s22 @Health.gov.au>; s22 s22 @health.gov.au>; s22 @health.gov.au>
Subject: RE: Implement a "Fail validation" rule for Trolamine salicylate [SEC=OFFICIAL]

This is done. Is it also due to a safety concern for our records in the rule itself?

Cheers

s22
Assistant Director – Business Improvement and Support Section
Complementary and OTC Medicines Branch

Medicine Regulation Division | Health Products Regulation Group
Australian Government Department of Health and Aged Care

T: s22 | E: s22 @health.gov.au

Location: Gulgana 1 South
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From: s22 @Health.gov.au>
Sent: Wednesday, July 31, 2024 12:57 PM
To: COMB Systems <COMB.SYSTEMS@HEALTH.GOV.AU>
Cc: s22 @Health.gov.au>; s22 s22 @health.gov.au>; s22 @health.gov.au>
Subject: Implement a "Fail validation" rule for Trolamine salicylate [SEC=OFFICIAL]

Good afternoon COMB Systems Team,

Can you please set up a “Fail validation” rule for Trolamine salicylate, with the fail message: “*Trolamine salicylate is under review. Please contact complementary.medicines@health.gov.au for further information*”?

As we did for *Caulophyllum thalictroides* (please see attached).

Thanks

s22

From: IRRS
To: s22
Subject: RE: Request for literature search: Trolamine salicylate [SEC=OFFICIAL]
Date: Friday, 16 August 2024 9:27:25 AM
Attachments: image001.png
image002.png
image004.png
Sunscreen Trolamine salicylate.doc

Hi s22

Sorry for the delay, the database didn't want to send your results for some reason.
I had to export them in a different format.
138 possibly relevant articles are attached.

Regards
s22
Senior Librarian – Information Resources and Research Services (IRRS)
Committees and Research Services Section
Regulatory Engagement Branch

Regulatory Practice and Support Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
T: s22 | E: s22 @health.gov.au
Location: Scherger Drive, Fairbairn
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The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 @Health.gov.au>
Sent: Thursday, August 8, 2024 12:43 PM
To: IRRS <IRRS@health.gov.au>
Subject: Request for literature search: Trolamine salicylate [SEC=OFFICIAL]

Good afternoon

Can you please help me by conducting a literature search in relation to the below?

- Ingredient name: Trolamine salicylate
- Keywords: "sunscreen", "dermal carcinogenicity", "systemic carcinogenicity", "developmental and reproductive toxicity", "toxicokinetics", "endocrine effects", "safety", "chronic exposure", "dermal irritation", "dermal sensitisation", and "phototoxicity".

Please let me know if you require any further details.

Thanks

s22

Database: Embase <1974 to 2024 August 14>, Ovid MEDLINE(R) ALL <1946 to August 14, 2024>

Search Strategy:

1 Trolamine salicylate.mp. (45)

2 exp triethanolamine salicylate/ (181)

3 "Triethanolamine salicylate".mp. (190)

4 2174-16-5.rn. (180)

5 "TEA salicylate".mp. (4)

6 1 or 2 or 3 or 4 or 5 (209)

7 exp drug carcinogenicity/ (929)

8 exp carcinogenicity/ (40448)

9 exp carcinogen/ (303112)

10 exp Carcinogens/ (303112)

11 exp Carcinogenicity Tests/ (8858)

12 exp Mutagens/ (116250)

13 exp mutagenicity tests/ (67699)

14 exp genotoxicity/ (42058)

15 exp Neoplasms/ (9838063)

16 ((Dermal or systemic) adj2 carcinog*).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kf, fx, dq, bt, nm, ox, px, rx, ui, sy, ux, mx] (463)

17 Carcinog*.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kf, fx, dq, bt, nm, ox, px, rx, ui, sy, ux, mx] (665931)

18 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 (10290891)

19 6 and 18 (55)

20 exp drug toxicity/ (302840)

21 exp reproductive toxicity/ (15054)

22 exp toxicity/ (821096)

23 exp toxicity testing/ (92614)

24 exp acute toxicity/ (29068)

25 exp developmental toxicity/ (5272)

26 exp Toxicity Tests/ (212062)

27 exp Toxicology/ (99379)

28 exp teratogens/ (63243)

29 exp teratogen/ (63243)

30 exp teratogenesis/ (12889)

31 exp teratogenicity/ (18674)

32 ((Development* or reproduct*) adj3 toxic*).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kf, fx,

dq, bt, nm, ox, px, rx, ui, sy, ux, mx] (49676)

33 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 (1291450)

34 6 and 33 (28)

35 exp toxicokinetics/ (14496)

36 Toxicokinetic*.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kf, fx, dq, bt, nm, ox, px, rx, ui, sy, ux, mx] (21797)

37 35 or 36 (21797)

38 6 and 37 (0)

39 exp endocrine function/ (582326)

40 exp endocrine disease/ (3773162)

41 exp endocrine system/ (1352877)

42 exp Endocrine Disruptors/ (22869)

43 (("long term" or endocrin*) adj3 effect*).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kf, fx, dq, bt, nm, ox, px, rx, ui, sy, ux, mx] (256418)

44 39 or 40 or 41 or 42 or 43 (5226856)

45 6 and 44 (18)

46 exp contact dermatitis/ (69456)

47 exp skin allergy/ (5295)

48 exp skin toxicity/ (26387)

49 exp skin irritation/ (18939)

50 exp skin sensitization/ (7444)

51 exp sensitization/ (87549)

52 exp photodermatosis/ (12830)

53 exp application site reaction/ (6053)

54 exp application site inflammation/ (105)

55 exp Skin Irritancy Tests/ (93407)

56 exp Skin Tests/ (145430)

57 exp skin pruritus/ (5159)

58 exp pruritus/ (143369)

59 exp allergic rash/ (472)

60 exp contact allergy/ (9000)

61 exp contact dermatitis/ (69456)

62 exp drug hypersensitivity/ (140696)

63 exp allergy/ (634627)

64 exp Hypersensitivity/ (1139661)

65 exp Allergens/ (128031)

66 ((dermal or skin) adj3 (sensiti* or irritat*)).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kf, fx, dq, bt, nm, ox, px, rx, ui, sy, ux, mx] (49579)

67 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62 or 63 or 64 or 65 or 66 (1576164)
68 6 and 67 (60)
69 exp phototoxicity/ (11037)
70 exp photoallergy/ (3655)
71 (phototox* or photoalle*).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kf, fx, dq, bt, nm, ox, px, rx, ui, sy, ux, mx] (24019)
72 69 or 70 or 71 (24019)
73 6 and 72 (15)
74 exp drug bioavailability/ (82684)
75 exp bioavailability/ (190724)
76 exp drug absorption/ (94994)
77 exp pharmacokinetics/ (1213801)
78 exp Skin Absorption/ (21307)
79 exp Biological Availability/ (190724)
80 exp Absorption, Physiological/ (164045)
81 (absorp* or absorb*).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kf, fx, dq, bt, nm, ox, px, rx, ui, sy, ux, mx] (1301372)
82 (penetration or penetrate or permeability).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kf, fx, dq, bt, nm, ox, px, rx, ui, sy, ux, mx] (691829)
83 (penetration or penetrate or permeability).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kf, fx, dq, bt, nm, ox, px, rx, ui, sy, ux, mx] (691829)
84 bioavail*.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kf, fx, dq, bt, nm, ox, px, rx, ui, sy, ux, mx] (301517)
85 74 or 75 or 76 or 77 or 78 or 79 or 80 or 81 or 82 or 83 or 84 (2966375)
86 6 and 85 (72)
87 (safe or safety or "side effect" or "side effects" or adverse).mp. or exp adverse drug reaction/ or exp drug-related side effects/ or exp drug safety/ or toxic*.mp. or hazard*.mp. (10828280)
88 6 and 87 (101)
89 19 or 34 or 38 or 45 or 68 or 73 or 86 or 88 (161)
90 remove duplicates from 89 (149)
91 limit 90 to english language (138)

1.

Insight into Mantle Cell Lymphoma Pathobiology, Diagnosis, and Treatment Using Network-Based and Drug-Repurposing Approaches.

Orfanoudaki G., Psatha K., Aivaliotis M.

Embase
International Journal of Molecular Sciences. 25(13) (no pagination), 2024. Article Number: 7298. Date of Publication: July 2024.

[Article]

AN: 2030574444

Mantle cell lymphoma (MCL) is a rare, incurable, and aggressive B-cell non-Hodgkin lymphoma (NHL). Early MCL diagnosis and treatment is critical and puzzling due to inter/intra-tumoral heterogeneity and limited understanding of the underlying molecular mechanisms. We developed and applied a multifaceted analysis of selected publicly available transcriptomic data of well-defined MCL stages, integrating network-based methods for pathway enrichment analysis, co-expression module alignment, drug repurposing, and prediction of effective drug combinations. We demonstrate the "butterfly effect" emerging from a small set of initially differentially expressed genes, rapidly expanding into numerous deregulated cellular processes, signaling pathways, and core machineries as MCL becomes aggressive. We explore pathogenicity-related signaling circuits by detecting common co-expression modules in MCL stages, pointing out, among others, the role of VEGFA and SPARC proteins in MCL progression and recommend further study of precise drug combinations. Our findings highlight the benefit that can be leveraged by such an approach for better understanding pathobiology and identifying high-priority novel diagnostic and prognostic biomarkers, drug targets, and efficacious combination therapies against MCL that should be further validated for their clinical impact.

PMID: 39000404 [https://www.ncbi.nlm.nih.gov/pubmed/?term=39000404]

Status: Embase

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Institution: (Orfanoudaki, Psatha, Aivaliotis) Functional Proteomics and Systems Biology (FunPATh), Center for Interdisciplinary Research and Innovation (CIRI-AUTH), Balkan Center, Thessaloniki GR-54124, Greece (Orfanoudaki, Psatha, Aivaliotis) Institute of Molecular Biology and Biotechnology Foundation for Research and Technology-Hellas, Heraklion GR-70013, Greece
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(Aivaliotis) Basic and Translational Research Unit, Special Unit for Biomedical Research and Education, School of Medicine, Aristotle University of Thessaloniki, Thessaloniki GR-54124, Greece
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Publisher: Multidisciplinary Digital Publishing Institute (MDPI)

Clinical Trial Number: https://clinicaltrials.gov/show/NCT00924326

Year of Publication: 2024

Link to the Ovid Full Text or citation:
Click here for full text options

2.

Risk of bleeding with concomitant use of oral anticoagulants and aspirin: A systematic review and meta-analysis.

Ghule P., Panic J., Malone D.C.

Embase
American Journal of Health-System Pharmacy. 81(12) (pp 494-508), 2024. Date of Publication: 15 Jun 2024.

[Article]

AN: 2032774912

Purpose: Oral anticoagulants (OACs) and aspirin can trigger bleeding events when used alone or in combination. The purpose of this study was to compare the risk of any type of bleeding in individuals exposed to a combination of OAC and aspirin with the risk in those taking an OAC or aspirin alone.
Method(s): MEDLINE and Web of Science were queried in January 2021 for eligible articles. Studies were included if they were either randomized controlled trials (RCTs) or observational studies and evaluated the number of any bleeding events in two groups, one with exposure to both OAC and aspirin and one with exposure to OAC alone or aspirin alone. Pooled odds ratios were calculated using a random-effects model.
Result(s): Forty-two studies were included. In an analysis of 15 RCTs and 19 observational studies evaluating OAC plus aspirin versus OAC alone, a significant difference in the risk of bleeding was observed in the combination groups, with an odds ratio [OR] of, 1.36 (95% CI, 1.15-1.59) for RCTs and an OR of 1.42 (95% CI-, 1.09-1.87) for observational studies. When OAC plus aspirin was compared to aspirin alone, a higher rate of bleeding was found in the combination group (OR, 2.36; 95%CI, 1.91-2.92) in the analysis of 15 RCTs, but no significant difference was found among 10 observational studies (OR, 1.93; 95% CI, 0.99-3.75).
Conclusion(s): The risk of any type of bleeding was significantly increased among patients taking aspirin plus OAC compared to those taking OAC alone in both RCTs and observational studies. Evaluation of RCTs comparing OAC plus aspirin to aspirin alone suggests increased bleeding risk as well.

PMID: 38263263 [https://www.ncbi.nlm.nih.gov/pubmed/?term=38263263]

Status: Embase

Institution: (Ghule, Malone) College of Pharmacy, University of Utah, Salt Lake City, UT, United States (Panic) Froedtert and the Medical College of Wisconsin, Milwaukee, WI, United States

Publisher: Oxford University Press

Year of Publication: 2024

Link to the Ovid Full Text or citation:
Click here for full text options

3.

Ultraviolet Filters: Dissecting Current Facts and Myths.

Breakell T., Kowalski I., Foerster Y., Kramer R., Erdmann M., Berking C., Heppt M.V.

Embase
Journal of Clinical Medicine. 13(10) (no pagination), 2024. Article Number: 2986. Date of Publication: May 2024.

[Review]

AN: 2029937617

Skin cancer is a global and increasingly prevalent issue, causing significant individual and economic damage. UV filters in sunscreens play a major role in mitigating the risks that solar ultraviolet ra-diation poses to the human organism. While empirically effective, multiple adverse effects of these compounds are discussed in the media and in scientific research. UV filters are blamed for the dis-ruption of endocrine processes and vitamin D synthesis, damaging effects on the environment, induction of acne and neurotoxic and carcinogenic effects. Some of these allegations are based on scientific facts while others are simply arbitrary. This is especially dangerous considering the risks of exposing unprotected skin to the sun. In summary, UV filters approved by the respective governing bodies are safe for human use and their proven skin cancer-preventing properties make them in-dispensable for sensible sun protection habits. Nonetheless, compounds like octocrylene and ben-zophenone-3 that are linked to the harming of marine ecosystems could be omitted from skin care regimens in favor of the myriad of non-toxic UV filters.

Status: Embase

Author NameID: Erdmann, Michael; ORCID: https://orcid.org/0000-0001-7136-6489
Berking, Carola; ORCID: https://orcid.org/0000-0003-0229-8931
Heppt, Markus V.; ORCID: https://orcid.org/0000-0003-4603-1825

Institution: (Breakell, Kowalski, Foerster, Kramer, Erdmann, Berking, Heppt) Department of Dermatology, Uniklinikum Erlangen, Friedrich-Alexander-Universitat Erlangen-Nurnberg, Erlangen 91054, Germany (Breakell, Kowalski, Foerster, Kramer, Erdmann, Berking, Heppt) Comprehensive Cancer Center Erlangen-European Metropolitan Area of Nuremberg (CCC ER-EMN) and CCC Alliance WERA, Erlangen 91054, Germany
(Breakell, Kowalski, Foerster, Kramer, Erdmann, Berking, Heppt) Bavarian Cancer Research Center (BZKF), Erlangen 91052, Germany
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Publisher: Multidisciplinary Digital Publishing Institute (MDPI)

Year of Publication: 2024

Link to the Ovid Full Text or citation:
Click here for full text options

4.

Sunscreens Part 2: Regulation and Safety.

Abdel Azim S., Bainvoll L., Vecerek N., DeLeo V.A., Adler B.L.

Embase
Journal of the American Academy of Dermatology. (no pagination), 2024. Date of Publication: 20 May 2024.

[Review]

AN: 644338730

The second part of this CME article discusses sunscreen regulation and safety considerations for humans and the environment. First, we provide an overview of the history of the United States Food and Drug Administration's regulation of sunscreen. Recent Food and Drug Administration studies clearly demonstrate that organic ultraviolet filters are systemically absorbed during routine sunscreen use, but to date there is no evidence of

associated negative health effects. We also review the current evidence of sunscreen's association with vitamin D levels and frontal fibrosing alopecia, and recent concerns regarding benzene contamination. Finally, we review the possible environmental effects of ultraviolet filters, particularly coral bleaching. While climate change has been shown to be the primary driver of coral bleaching, laboratory-based studies suggest that organic ultraviolet filters represent an additional contributing factor, which led several localities to ban certain organic filters.

PMID: 38777185 [https://www.ncbi.nlm.nih.gov/pubmed/?term=38777185]

Status: Article-in-Press

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Year of Publication: 2024

Link to the Ovid Full Text or citation:
Click here for full text options

5.

In vitro evaluation of metabolism- and transporter-based drug interactions with sunscreen active ingredients.

Volpe D., Qusa M.

Embase
Drug Metabolism and Pharmacokinetics. Conference: 25th North American ISSX Meeting. Boston United States. 55(Supplement) (no pagination), 2024. Article Number: 100877. Date of Publication: April 2024.

[Conference Abstract]

AN: 2032211101

Introduction: Percutaneously absorbed sunscreen active ingredients may have the potential to interact with other concomitantly administered drugs in humans. The aim of this study was to examine the inhibition potential of sunscreen active ingredients on drug metabolism catalyzed by cytochrome P450 (CYP) enzymes and on hepatic and renal uptake transporters.
Method(s): In vitro metabolism assays with human liver microsomes were conducted for CYP3A4, CYP2D6 and CYP2C9 with probe substrates midazolam, bufuralol and warfarin, respectively. In vitro uptake assays with transfected cell lines were conducted for OATP1B1, OCT2 and OAT3 with probe substrates rosuvastatin, metformin and estrone-3-sulfate, respectively. CYP and transport inhibition by selected sunscreen ingredients were compared to known positive control inhibitors. Six sunscreen active ingredients, avobenzone, homosalate, octinoxate, oxybenzone, trolamine salicylate, and enzacamene, were evaluated up to their aqueous solubility limits in the assays.
Result(s): The positive control inhibitors ketoconazole (CYP3A4), quinidine (CYP2D6) and sulphaphenazole (CYP2C9) had IC50 values of 0.020, 0.047 and 0.041 mug/mL. None of the six sunscreens inhibited CYP3A4 or CYP2D6 activities in the microsomes at concentration ranges up to 10-fold higher than known plasma levels. Enzacamene, oxybenzone and trolamine were found to be inhibitory to CYP2C9 activity with IC50 values of 4.184, 4.687 and 0.107 mug/mL, respectively. The positive control inhibitors cyclosporine (OATP1B1), cimetidine (OCT2) and probenecid (OAT3) had IC50 values of 4.8, 4.1 and 2.56 mug/mL in the uptake transport assays. Oxybenzone and trolamine were found to be inhibitory to OCT2 activity with IC50 values of 2.3 and 94 mug/mL, respectively, and inhibitory to OAT3 activity with IC50 values of 9 and 128 mug/mL, respectively.
Conclusion(s): The in vitro metabolism assay demonstrated that sunscreen active ingredients were less inhibitory to CYP metabolism than the positive controls for CYP3A4, CYP2D6 and CYP2C9. Although enzacamene, oxybenzone and trolamine inhibited CYP2C9 in vitro, their IC50 values are very high compared to known clinical plasma levels. The sunscreen active ingredients are also less inhibitory to OCT2 and OAT3 uptake than their positive control inhibitors. Oxybenzone and trolamine also had slight inhibitory effects on the OCT2 and OAT3 transporters with very high IC50 values compared to known clinical plasma levels. While there was some inhibition of the evaluated CYP enzymes and transporters by the sunscreen ingredients, these effects were observed at concentrations that exceeded plasma levels found in clinical studies.

Status: CONFERENCE ABSTRACT

Institution: (Volpe, Qusa) Food and Drug Administration, Silver Spring, MD, United States

Publisher: Japanese Society for the Study of Xenobiotics

Year of Publication: 2024

Link to the Ovid Full Text or citation:
Click here for full text options

6.

Photodermatoses in patients with atopic dermatitis: A 10-year retrospective cohort study.

Afvari S., Zippin J.H.

Embase
Journal of the American Academy of Dermatology. 90(5) (pp 1071-1074), 2024. Date of Publication: May 2024.

[Article]

AN: 2030540205

PMID: 38372681 [https://www.ncbi.nlm.nih.gov/pubmed/?term=38372681]

Status: Embase

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Publisher: Elsevier Inc.

Year of Publication: 2024

Link to the Ovid Full Text or citation:
Click here for full text options

7.

Comparison of the efficacy among different interventions for radiodermatitis: A Bayesian network meta-analysis of randomized controlled trials.

Guan Y., Liu S., Li A., Cheng W.

Embase
PLoS ONE. 19(4 April) (no pagination), 2024. Article Number: e0298209. Date of Publication: April 2024.

[Article]

AN: 2031649907

Background Radiation dermatitis (RD) is a prevalent and difficult-to-manage consequence of radiation therapy (RT). A variety of interventions have been proven effective in preventing and treating RD. However, the optimal approach remains unclear. This network meta-analysis (NMA) conducted a comparison and ranking of the effectiveness and patient-reported outcomes (PROs) of the interventions currently utilized in RD. Methods PubMed, Web of Science, Embase, and Cochrane Library were searched to identify pertinent randomized controlled trials (RCTs) focused on the prevention and treatment of RD. The primary outcome measures included the incidence of grade >=2 RD (i.e., percentage of moist desquamation) and RD score. The secondary outcome measures encompassed patients' subjective assessment scores of pains, itching and burning sensations. Results Our meta-analysis encompassed 42 studies and 4884 participants. Regarding the primary outcomes, photobiomodulation treatment (PBMT) ranked first in surface under curve cumulative ranking area (SUCRA:0.92) for reducing the incidence of grade>=2 RD. It demonstrated a significant difference when compared to Trolamine (OR 0.18,95%CrI 0.09-0.33) and Xonrid (OR 0.28,95%CrI 0.12-0.66). Mepitelfilm (SUCRA: 0.98) achieved the highest rank in reducing the RD score, demonstrating superiority over StrataXRT (MD -0.89, 95% CrI -1.49, -0.29). Henna (SUCRA: 0.89) demonstrated the highest effectiveness in providing pain relief, with a significant difference compared to Hydrofilm (MD -0.44, 95% CrI -0.84, -0.04) and Mepitelfilm

(MD -0.55, 95% CrI -0.91, -0.19). Hydrofilm (SUCRA: 0.84) exhibited the fewest itching sensations, demonstrating superiority over Mepitelfilm (MD -0.50, 95% CrI -0.84, -0.17). No statistically significant difference was observed among various interventions in the assessment of burning sensations. Conclusion PBMT and Mepitelfilm demonstrated better efficacy in reducing the incidence of grade>=2 RD and RD score, respectively. In terms of PROs, Henna and Hydrofilm had fewer complaints in pain and itching sensations, respectively. However, studies with larger sample size on different interventions are warranted in the future.

PMID: 38598529 [https://www.ncbi.nlm.nih.gov/pubmed/?term=38598529]

Status: Embase

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(Cheng) Department of Radiation Oncology, Shunde Hospital, Southern Medical University, Shunde, China

Publisher: Public Library of Science

Year of Publication: 2024

Link to the Ovid Full Text or citation:
Click here for full text options

8.

The Role of Cnidocytes in Transdermal Drug Delivery: A Systematic Review.

Shivnani V.A.

Embase
International Journal of Pharmaceutical and Clinical Research. 16(1) (pp 56-62), 2024. Date of Publication: 2024.

[Review]

AN: 2027794292

Cnidaria is a water-dwelling phylum characterized by a cnidocyte stinging cell. In nature, cnidocytes are used to immobilize or "sting" prey, for defense, and for locomotion, but their mechanisms also hold implications for drug delivery. Oral drug delivery has limitations that warrant new drug delivery techniques. One prominent method, transdermal drug delivery, uses the skin as a drug administration platform. Drugs can be systemically absorbed through microcirculation after relatively less invasive, painless, and self-administered delivery through ointments, creams, patches, and microneedles. Research has shown microneedle technology (essentially arrays of miniature needles) could implement cnidarian cnidocytes to bypass current microneedle restraints. Although positive results support cnidocyte gel-based drug delivery, limited variety formulas, conditions, and drugs have been tested, warranting future research before widespread implementation.

Status: Embase

Institution: (Shivnani) Shepton High School, Plano, TX, United States

Publisher: Dr. Yashwant Research Labs Pvt. Ltd.

Year of Publication: 2024

Link to the Ovid Full Text or citation:
Click here for full text options

9.

Geospatial and co-occurrence analysis of antibiotics, hormones, and UV filters in the Chesapeake Bay (USA) to confirm inputs from wastewater treatment plants, septic systems, and animal feeding operations.

Hain E., He K., Batista-Andrade J.A., Feerick A., Tarnowski M., Timm A., Blaney L.

Embase
Journal of Hazardous Materials. 460(no pagination), 2023. Article Number: 132405. Date of Publication: 15 Oct 2023.

[Article]

AN: 2026675813

Previous studies have reported select contaminants of emerging concern (CECs) in limited areas of the Chesapeake Bay (USA), but no comprehensive efforts have been conducted. In this work, 43 antibiotics, 9 hormones, 11 UV filters, and sucralose, were measured in matched water, sediment, and oyster samples from 58 sites. The highest sucralose concentration was 3051 ng L-1 in a subwatershed with 4.43 million liters of wastewater effluent per day (MLD) and 4385 septic systems. Although antibiotic occurrence was generally low in subwatersheds located in less populated areas, 102 ng L-1 ciprofloxacin was detected downstream of 0.58 MLD wastewater effluent and 10 animal feeding operations. Hormones were not regularly detected in water (2%) or oysters (37%), but the high detection frequencies in sediment (74%) were associated with septic systems. UV filters were ubiquitously detected in oysters, and octisalate exhibited the highest concentration (423 ng g-1). Oyster-phase oxybenzone and aqueous-phase sucralose concentrations were significantly correlated to wastewater effluent and septic systems, respectively. Toxicity outcomes were predicted for homosalate and octisalate throughout the Bay, and antimicrobial resistance concerns were noted for the Chester River. The geospatial and co-occurrence relationships constitute crucial advances to understanding CEC occurrence in the Chesapeake Bay and elsewhere.

PMID: 37651932 [https://www.ncbi.nlm.nih.gov/pubmed/?term=37651932]

Status: Embase

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Publisher: Elsevier B.V.

Year of Publication: 2023

10.

Euglena gracilis Extract Protects From Tobacco Smoke Carcinogen-Induced Lung Cancer by Altering Gut Microbiota Metabolome.

Upreti D., Ishiguro S., Phillips M., Nakashima A., Suzuki K., Comer J., Tamura M.

Embase
Integrative Cancer Therapies. 22(no pagination), 2023. Date of Publication: January-December 2023.

[Article]

AN: 2025198889

Extracts from Euglena gracilis have been shown to prevent cancer growth in mouse models. However, the molecular mechanism of this anti-cancer activity has not been determined nor has the effect of Euglena extracts on tobacco smoke carcinogen-induced carcinogenesis. Here, we investigate the hypothesis that this anti-cancer activity is a result of changes in the

intestinal microbiota induced by oral administration of the extract. We found that a Euglena gracilis water extract prevents lung tumorigenesis induced by a tobacco smoke-specific carcinogen (NNK) in mice treated either 2 weeks before or 10 weeks after NNK injection. Both of these treatment regimens are associated with significant increases in 27 microbiota metabolites found in the mouse feces, including large increases in triethanolamine, salicylate, desaminotyrosine, N-acetylserine, glycolate, and aspartate. Increases in the short-chain fatty acids (SCFAs) including acetate, propionate and butyrate are also observed. We also detected a significant attenuation of lung carcinoma cell growth through the induction of cell cycle arrest and apoptosis caused by low levels of SCFAs. This study provides strong evidence of anti-cancer activity in Euglena gracilis extracts against tobacco smoke carcinogen-induced tumorigenesis and demonstrates that this activity is linked to increased production of specific gut microbiota metabolites and the resultant induction of cell cycle arrest and apoptosis of lung carcinoma cells.

PMID: 37646331 [https://www.ncbi.nlm.nih.gov/pubmed/?term=37646331]

Status: Embase

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Publisher: SAGE Publications Inc.

Year of Publication: 2023

11.

Open-Label Adhesion Performance Study of a Prescription Lidocaine Topical System 1.8% versus Three Lidocaine-Containing Over-the-Counter Patches in Healthy Subjects.

Fudin J., Vought K., Patel K., Lissin D., Maibach H.

Embase
Journal of Pain Research. 15(pp 2051-2065), 2022. Date of Publication: 2022.

[Article]

AN: 2017584616

Purpose: This study evaluates and compares the clinical adhesion performance of a prescription lidocaine topical system 1.8% versus two different over-the-counter (OTC) lidocaine patches 4% and an OTC combination menthol and lidocaine patch 1%/4% in human subjects.

Patients and Methods: This study was an open-label, randomized, four-treatment, four-sequence, Phase 1 adhesion performance study in healthy adult volunteers (N = 24). Lidocaine topical system 1.8% (R) and the three OTC patch products (T1, T2, and T3) were separately applied for 12 hours. Adhesion of all products was scored at 0, 3, 6, 8, and 12 hours post-application.
Result(s): There were no issues with the conduct of the study. Overall, the majority (>=59.1%) of subjects treated ("patched") with the lidocaine topical system 1.8% (R) demonstrated >=90% adhesion (FDA adhesion score 0) throughout the 12-hour administration period versus 27.3% of subjects treated with OTC lidocaine patch 4% (T1), 22.7% of subjects treated with OTC lidocaine patch 4% (T2), and 18.2% of subjects treated with OTC menthol/lidocaine patch 1%/4%. Only one subject (4.5%) treated with lidocaine topical system 1.8% was observed with <75% adhesion (FDA adhesion score <2) versus 11 (50.0%) and 10 (45.5%) for the two OTC lidocaine patches 4% (T1 and T2), respectively, and 13 (59.1%) subjects for the OTC menthol/lidocaine patch 1%/4%. There were no complete detachments observed for lidocaine topical system 1.8%, whereas 50.0% and 31.8% complete detachments were observed for the two OTC lidocaine patches 4% (T1 and T2), and 27.3% complete detachments were observed for the OTC menthol/lidocaine patch 1%/4%. No adverse events were observed for any of the treatments.
Conclusion(s): Lidocaine topical system 1.8% demonstrated superior adhesion relative to the three lidocaine-containing OTC products over the 12-hour treatment period.

Status: Embase

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Publisher: Dove Medical Press Ltd

Clinical Trial Number: https://clinicaltrials.gov/show/NCT05106400

Year of Publication: 2022

Link to the Ovid Full Text or citation:
Click here for full text options

12.

Hyperpigmentation: Looking beyond hydroquinone.

Charoo N.A.

Embase
Journal of Cosmetic Dermatology. 21(10) (pp 4133-4145), 2022. Date of Publication: October 2022.

[Review]

AN: 2014715318

Hyperpigmentation is the most common complaint in the age group 40-45 years, seeking consultation for skin disorders. Hydroquinone is a commonly used depigmenting agent in clinical practice for treating hyperpigmentation. Prolonged use of hydroquinone has been associated with cancer risk and exogenous ochronosis. The CARES (The Coronavirus Aid,

Relief, and Economic Security Act) Act of 2020 has instituted significant changes to hydroquinone containing OTC (over the counter) products, and consequently, many hydroquinone-based OTC products had to be withdrawn from the market. Henceforth, products containing hydroquinone would need US Food and Drug Administration approval via new drug application pathways for commercialization. Alternative treatment options to hydroquinone in clinical practice are reviewed in this paper with regard to their safety and efficacy vis a vis hydroquinone. Also, new potential treatment options such as thiamidol, Polypodium leucotomos, and glutathione are discussed. The review shows that these alternative depigmenting agents can be rationally combined to achieve desired treatment goals in the management of hyperpigmentation.

PMID: 35020267 [https://www.ncbi.nlm.nih.gov/pubmed/?term=35020267]

Status: Embase

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Publisher: John Wiley and Sons Inc

Year of Publication: 2022

Link to the Ovid Full Text or citation:
Click here for full text options

13.

Treatment Strategies for Generator Pocket Pain.

Bao J., Khazen O., Olmsted Z.T., Gechtman G., Shao M.M., DiMarzio M., Topp G., Sukul V.V., Staudt M.D., Pilitsis J.G.

Embase
Pain Medicine (United States). 22(6) (pp 1305-1311), 2021. Date of Publication: 01 Jun 2021.

[Article]

AN: 2021803304

Objective: Generator site pain is a relatively common phenomenon in patients undergoing spinal cord stimulation (SCS) that complicates management and effective pain relief. This pain may be managed conservatively, with repositioning of the battery and, in some cases, with explant. Here we explore our experience with management of generator site pain ("pocket pain") in a large single-center study.
Method(s): All SCS permanent implants and implantable pulse generator (IPG) placements over 9 years were reviewed. Of 785 cases, we identified 43 patients with pocket pain (5.5%). Demographics and treatments of the pocket pain cohort were analyzed.
Result(s): The mean age (+/- SEM) of the pocket pain cohort was 46.86 +/- 1.06, and there were 10/33 males/females. Females were overrepresented in pocket pain cohort (76.7%) when compared with the total SCS cohort (59.0%) ($X2 = 5.93$, $P = 0.015$). Diagnosis included failed back surgery syndrome (51.2%), complex regional pain syndrome (23.3%), and chronic neuropathic pain (25.5%). No patients improved with conservative therapy. All patients either went on to revision (n = 23) or explant (n = 20). Time from initial surgery to development of pocket pain was 7.5 months (range: 0.3-88) and from pocket pain to revision surgery was 4.5 months (range: 0.4-26). In addition, significantly more pocket pain patients (65.1%) had workers' compensation (WC) insurance compared with patients without pocket pain (24.9%) ($X2 = 33.3$, $P < 0.001$).
Conclusion(s): In our institutional experience, pocket pain was inadequately managed with conservative treatments. Being female and having SCS filed under WC increased risk of pocket pain. Future work will explore the nuances in device placement based on body shape and manual activity responsibilities.

PMID: 33502508 [https://www.ncbi.nlm.nih.gov/pubmed/?term=33502508]

Status: Embase

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Publisher: Oxford University Press

Year of Publication: 2021

Link to the Ovid Full Text or citation:
Click here for full text options

14.

Microsponge Drug Delivery System: Emerging Technique in Novel Drug Delivery System and Recent Advances.

Choudhary A., Akhtar M.S.

Embase
Research Journal of Pharmacy and Technology. 15(10) (pp 4835-4840), 2022. Date of Publication: October 2022.

[Review]

AN: 2018869137

A number of advancements have been made in the drug delivery system in order to achieve the goals of improved efficacy and cost-effectiveness in therapy. Controlling the rate of release of active drugs to a predetermined site in the human body has been one of the pharma industry's most challenging tasks. Microsponges are porous cross-linked, non-collapsible microspheres with a size range of 5-300microm that can entrap a variety of drugs and then be incorporated into a formulated product like gel, cream, powder, or liquid. Controlled release of drugs onto the epidermis with the confidence that the drug remains primarily localized and does not enter the systemic circulation in substantial amounts is a field of research that the microsponge delivery system is progressively exploring. In order to remove systemic exposure and minimize local cutaneous reaction to active drugs, microsponge technology has been introduced in topical drug products to facilitate the controlled release of the active drugs into the cell. Also, numerous studies have shown that microsponge systems are non-irritating, non-mutagenic, non-allergenic, and non-toxic. MDDS technology is being used currently in cosmetics, over-the-counter (OTC) skin care,

sunscreens, and prescription products and has recently been used in oral drugs as well as biopharmaceuticals (protein, peptides, and DNA based therapeutics) drug delivery. The purpose of this article is to provide information about microsponges such as the method of preparation, mechanism of drug release from microsponges, characterization, applications of microsponges, and information about microsponges updated research.

Status: Embase

Institution: (Choudhary, Akhtar) Shri Ram Murti Smarak College of Engineering and Technology, (Pharmacy), Uttar Pradesh, Bareilly 243202, India

Publisher: Research Journal of Pharmacy and Technology

Year of Publication: 2022

Link to the Ovid Full Text or citation:
Click here for full text options

15.

Formulation and Evaluation of Trolamine Salicylate Microemulsion.

Sharma P., Farooqui N., Jamindar D., Paliwal P., Mishra D.K.

Embase
Asian Journal of Pharmaceutics. 16(3) (pp 342-347), 2022. Date of Publication: July 2022.

[Article]

AN: 2021093030

Aim: The aim of this study was to formulate and perform optimization, characterization, and in-vitro evaluation of microemulsion containing trolamine salicylate (TMS) an anti-inflammatory agent for topical application.
Material(s) and Method(s): Microemulsion formulations of TMS were prepared from optimized microemulsion and effects of formulation variables such as solubility in different

oils, surfactants and co-surfactants were assessed. Oleic acid was selected as oil phase, tween-80, and ethanol as surfactant and cosurfactant, respectively. From the ternary phase diagrams of surfactant (Tween 80)/cosurfactant (Ethanol) 1:1 ratio and oil (oleic acid), TMS-loaded microemulsion formulation A6* was selected on the basis of clarity. Results and Discussion: The microemulsion formulation A6* was found to be optically clear, transparent, and elegant in appearance, when compared to the other microemulsion formulations with pH values of 5.3-6.5 were showing suitability for topical preparations. The transmission electronic microscopy image of A6* showed that globules were spherical in shape, smooth surface, and indicated the existence of an isotropic dispersion of spherical droplets, leading to the assumption of inverse micelles because of the proportion of the constituents. Particle size of 297 nm indicates that there is a chance that the number of vesicles can interact with a fixed area of stratum corneum, thereby increasing the efficiency in percutaneous uptake. During Ex-vivo permeability study, the flux values and permeability coefficient of TMS Microemulsion (A-6*) were found to be 6.518 microg/cm2 h and 3.259 cm.h-1. The highest cumulative drug release for formulation A*6 was 95.048 +/- 0.032% in 8 h.
Conclusion(s): Microemulsion has low interfacial tension and allows excellent contact with skin surface, with the vehicle filling even wrinkles and microscopic gaps. This enhances the vehicle skin drug transfer. They have been used to improve the bioavailability of various poorly soluble drugs including non-steroidal anti-inflammatory drugs. The formulation was in nano range and hence the penetrability of the drug can be increased. Since this type of formulations can be easily developed and prepared; therefore, they can be of great help for the drugs that have less permeation across the skin. Among the distinctive formulations, A6* showed promising results, with respect to drug entrapment and percentage drug release.

Status: Embase

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Publisher: BRNSS Publication Hub

Year of Publication: 2022

Link to the Ovid Full Text or citation:
Click here for full text options

16.

Survey of off-label prescribing in a university paediatric outpatient in Brazil.

Monteiro F.A.S.G., Soares C.N., Chaveiro L.G., Cabral V.A., Lima P.M.A.

Embase
Tropical Doctor. 52(2) (pp 270-275), 2022. Date of Publication: April 2022.

[Article]

AN: 2014782802

Ours is a cross-sectional, descriptive, retrospective study evaluating the extent of off-label prescribing for patients attending a university paediatric outpatient department in Goias, Brazil. 391 patients were treated in the outpatient, and 668 medicines were prescribed. Of these, 70.4% followed the terms of the marketing authorization; 0.3% were unlicenced, and 11% were off-label. Dose was the main factor in off-label prescribing. Infants (0-2 years) received 37.8% of the off-label prescriptions. Vitamins and drugs for the treatment of respiratory diseases were the most prevalent culprits. Of the total prescriptions, 23 different drugs were defined as off-label. Salbutamol was the most prescribed (41.9%). Owing to practical and legal difficulties in carrying out clinical trials, medicines are inadequately studied in children; cooperation between industry, regulatory authorities, and healthcare professionals is required to improve treatment safety. Our results may help guide clinical researcher on off-label prescripting in future trials.

PMID: 35037806 [https://www.ncbi.nlm.nih.gov/pubmed/?term=35037806]

Status: Embase

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Publisher: SAGE Publications Ltd

Year of Publication: 2022

Link to the Ovid Full Text or citation:
Click here for full text options

17.

Bart's syndrome associated with a disorder of sexual differentiation: An atypical presentation in a Cameroonian newborn.

Sigha O.B., Mbono Betoko R., Nkoro G.A., Fossi Happi M., Ekoube C.E., Kelbaba B.B., Mandeng Ma Linwa E., Kouotou E.A.

Embase
Clinical Case Reports. 10(1) (no pagination), 2022. Article Number: e05234. Date of Publication: January 2022.

[Article]

AN: 2014862335

Bart's syndrome consists of congenital aplasia of the skin affecting only the lower limbs, associated with bullae over the skin and/or mucous membranes, as well as a nail anomaly. It is an extremely rare genetic disorder, which can be associated with other birth defects. We report the case of a newborn baby admitted at day 0 of life in the neonatal department, for multifocal skin detachment predominantly at the lower limbs. In addition, examination of the external genitalia revealed a clitoridomegaly genital bud measuring 14 mm, scrotalized and unfused genital bulges with the presence of 2 orifices. No gonad was palpated. The clinical diagnosis of Bart's syndrome associated with a disorder of sexual differentiation was retained. We hereby report the first case of Bart's syndrome described in Cameroon in association with a disorder of sexual differentiation.

Status: Embase

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Publisher: John Wiley and Sons Inc

Year of Publication: 2022

Link to the Ovid Full Text or citation:
Click here for full text options

18.

Radiodermatitis and fibrosis in the context of breast radiation therapy: A critical review.

Allali S., Kirova Y.

Embase
Cancers. 13(23) (no pagination), 2021. Article Number: 5928. Date of Publication: December-1 2021.

[Review]

AN: 2014642533

Background: Radiation therapy has been progressively improved in order to maintain a satisfactory tumour response, while reducing toxicity. We will review the incidence of radiodermatitis and fibrosis according to the various radiation and fractionation techniques. We will then focus on the various methods used to manage, prevent, and quantify this toxicity.
Method(s): More than 1753 articles were identified using the various search terms. We selected 53 articles to answer the questions addressed in this study according to criteria set in advance.
Result(s): The literature reports lower acute toxicity with IMRT compared to 3DCRT, but no significant differences in terms of late toxicities. Partial breast irradiation appears to be less effective in terms of local control with a higher rate of late toxicity. Intra operative radiation therapy appears to provide good results in terms of both local control and late toxicity. The hypofractionation has equivalent efficacy and safety to the normofractionated regimen, but with lower rates of radiodermatitis and fibrosis. The adddition of a boost, particularly a sequential boost, increases the risk of fibrosis and radiodermatitis during treatment.
Conclusion(s): The development of IMRT has significantly reduced acute toxicity and has improved tolerability during treatment. Modified fractionation has reduced treatment time, as well as adverse effects.

Status: Embase

Institution: (Allali, Kirova) Radiation Therapy Department, Institut Curie, CEDEX 05, Paris 75248, France

Publisher: MDPI

Year of Publication: 2021

Link to the Ovid Full Text or citation:
Click here for full text options

19.

Dermatologic sequelae of breast cancer: From disease, surgery, and radiation.

Milam E.C., Rangel L.K., Pomeranz M.K.

Embase
International Journal of Dermatology. 60(4) (pp 394-406), 2021. Date of Publication: April 2021.

[Review]

AN: 2007442397

The care of breast cancer patients is important to dermatologists. Breast cancer's initial presentation, clinical progression, and its associated treatments can result in a variety of cutaneous complications. Dermatologists may be the first to identify a breast cancer diagnosis, as a subset of patients first present with direct extension of an underlying tumor or with a cutaneous metastasis. The surgical treatment of breast cancer also begets a variety of skin sequelae, including postoperative lymphedema, soft tissue infections, seromas, pyoderma gangrenosum, and scarring disorders. Moreover, breast cancer radiation treatment commonly results in skin changes, which can range from mild and temporary dermatoses to chronic and disfiguring skin ulceration, fibrosis, and necrosis. Radiation may also precipitate secondary malignancies, such as angiosarcoma, as well as rarer dermatologic diseases, such as radiation-induced morphea, lichen planus, and postirradiation pseudosclerodermatous panniculitis. Finally, breast cancer is also associated with an array of paraneoplastic phenomena, including Sweet's syndrome and the rarer intralymphatic histiocytosis. Herein, we review the dermatological manifestations of breast cancer, including conditions associated with its presentation, progression, and treatment sequelae. Chemotherapy-induced cutaneous side effects are beyond the scope of this review. This article provides a comprehensive review for dermatologist to be able to identify, diagnose, and manage breast cancer patients from initial presentation to treatment monitoring and subsequent follow-up.

PMID: 33226140 [https://www.ncbi.nlm.nih.gov/pubmed/?term=33226140]

Status: Embase

Institution: (Milam, Rangel, Pomeranz) The Ronald O. Perelman Department of Dermatology, New York University Grossman School of Medicine, New York, NY, United States

Publisher: John Wiley and Sons Inc

Year of Publication: 2021

Link to the Ovid Full Text or citation:
Click here for full text options

20.

The efficacy and safety of sunscreen use for the prevention of skin cancer.

Sander M., Burbidge T., Beecker J.

Embase
CMAJ. 192(50) (pp E1802-E1808), 2020. Date of Publication: 14 Dec 2020.

[Review]

AN: 2010448614

PMID: 33318091 [https://www.ncbi.nlm.nih.gov/pubmed/?term=33318091]

Status: Embase

Institution: (Sander, Burbidge) Department of Medicine, University of Calgary, Calgary, AB, Canada (Sander) Section of Dermatology, Cumming School of Medicine, University of Calgary, Calgary, AB, Canada
(Beecker) Division of Dermatology, Department of Medicine, Ottawa Hospital, Ottawa, ON, Canada
(Beecker) Faculty of Medicine, Ottawa, ON, United States
(Beecker) University of Ottawa, Ottawa Hospital Research institute, Ottawa, ON, Canada

Publisher: Canadian Medical Association

Year of Publication: 2020

Link to the Ovid Full Text or citation:
Click here for full text options

21.

"Over-the-counter" cannabidiol (CBD) sold in the community pharmacy setting in Colorado.

Shea L.A., Leeds M., Bui D., Mujica M., Poupard M., Rodriguez R., Matura J.M., Carnazzo A., Spence A.

Embase
Drugs and Therapy Perspectives. 36(12) (pp 573-582), 2020. Date of Publication: December 2020.

[Article]

AN: 2006834902

Introduction: The use of cannabidiol is becoming so popular that even pharmacies now carry over-the-counter (OTC) cannabidiol products in Colorado, USA.
Objective(s): The primary goal of this study was to evaluate cannabidiol products sold in the community pharmacy setting to determine the content of cannabidiol and other active ingredients and the safety information that may be provided to individuals considering the use of these products.
Method(s): Documentation of cannabidiol products available for purchase in pharmacies was compiled by visiting chain and independent pharmacies within the state of Colorado. Cannabidiol products were documented for claims of use, dose, route, administration, additional ingredients, and cost.
Result(s): In total, 60 cannabidiol products (15 oral, 44 topical, and one transdermal) were found in 35 pharmacies. The concentrations of oral cannabidiol varied from 10 to 60 mg/mL. In total, 13 (87%) of the oral products were labeled as "full spectrum." Six (40%) of the oral cannabidiol products listed medium-chain triglycerides, a compound with evidence of increasing oral bioavailability. The amount of cannabidiol labeled on topical products varied from 30 mg cannabidiol/15 mL to 1000 mg cannabidiol. Some products did not indicate any quantity of cannabidiol or did provide the amount of hemp extract/oil but did not specify how much cannabidiol was present. In total, 29 (66%) of the topical products contained additional active ingredients: arnica, camphor, capsaicin, menthol, peppermint oil, white willow bark

(salicylic acid), tea tree oil, and trolamine salicylate. Only one type of transdermal product for cannabidiol delivery was found, which provided a dose of 20 mg cannabidiol/24 h. Conclusion(s): The findings of this study illustrate the extensive variability of cannabidiol products and the importance of communication with people considering their use. Counseling those utilizing these products may help to avoid drug-drug or drug-supplement interactions and adverse events.

Status: Embase

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Publisher: Adis

Year of Publication: 2020

Link to the Ovid Full Text or citation:
Click here for full text options

22.

Osteoarthritis: New Strategies for Transport and Drug Delivery across Length Scales.

Ngo L., Knothe Tate M.L.

Embase
ACS Biomaterials Science and Engineering. 6(11) (pp 6009-6020), 2020. Date of Publication: 09 Nov 2020.

[Review]

AN: 2008582970

Osteoarthritis (OA) is the fourth leading cause of disability in adults. Yet, few viable pharmaceutical options exist for pain abatement and joint restoration, aside from joint replacement at late and irreversible stages of the disease. From the first onset of OA, as joint pain increases, individuals with arthritis increasingly reach for drug delivery solutions, from taking oral glycosaminoglycans (GAGs) bought over the counter from retail stores (e.g., Costco) to getting injections of viscous, GAG-containing synovial fluid supplement in the doctor's office. Little is known regarding the efficacy of delivery mode and/or treatment by such disease-modulating agents. This Review addresses the interplay of mechanics and biology on drug delivery to affected joints, which has profound implications for molecular transport in joint health and (patho)physiology. Multiscale systems biology approaches lend themselves to understand the relationship between the cell and joint health in OA and other joint (patho)physiologies. This Review first describes OA-related structural and functional changes in the context of the multilength scale anatomy of articular joints. It then summarizes and categorizes, by size and charge, published molecular transport studies, considering changes in permeability induced through inflammatory pathways. Finally, pharmacological interventions for OA are outlined in the context of molecular weights and modes of drug delivery. Taken together, the current state-of-the-art points to a need for new drug delivery strategies that harness systems-based interactions underpinning molecular transport and maintenance of joint structure and function at multiple length scales from molecular agents to cells, tissues, and tissue compartments which together make up articular joints. Cutting edge and cross-length and-time scale imaging represents a key discovery enabling technology in this process.

PMID: 33449636 [https://www.ncbi.nlm.nih.gov/pubmed/?term=33449636]

Status: Embase

Institution: (Knothe Tate) Inaugural Paul Trainor Chair of Biomedical Engineering, Graduate School of Biomedical Engineering, University of New South Wales, Sydney, NSW 2052, Australia (Ngo) Graduate School of Biomedical Engineering, University of New South Wales, Sydney, NSW 2052, Australia

Publisher: American Chemical Society

Year of Publication: 2020

Link to the Ovid Full Text or citation:
Click here for full text options

23.

Skin cancer prevention and sunscreen safety: Commentary on American Society of clinical oncology policy statement on skin cancer prevention.

Strauss D.G., Michele T.M.

Embase
JCO Oncology Practice. 16(8) (pp 436-438), 2020. Date of Publication: 2020.

[Review]

AN: 2007647549

PMID: 32603257 [https://www.ncbi.nlm.nih.gov/pubmed/?term=32603257]

Status: Embase

Institution: (Strauss) Division of Applied Regulatory Science, Office of Clinical Pharmacology, Office of Translational Sciences, Center for Drug Evaluation and Research, US Food and Drug Administration, Silver Spring, MD, United States (Michele) Office of Nonprescription Drugs, Office of New Drugs, Center for Drug Evaluation and Research, US Food and Drug Administration, Silver Spring, MD, United States

Publisher: American Society of Clinical Oncology (E-mail: jcoservice@asco.org)

Year of Publication: 2020

Link to the Ovid Full Text or citation:
Click here for full text options

24.

Common Toxidromes and the Role of Extracorporeal Detoxification.

Harbord N.

Embase
Advances in Chronic Kidney Disease. 27(1) (pp 11-17), 2020. Date of Publication: January 2020.

[Review]

AN: 2005133192

Extracorporeal modalities have been used for detoxification for decades, with hemodialysis the preferred and most commonly used modality. Salicylates, lithium, methanol, and ethylene glycol are the most common poisonings treated with dialysis. For each of these common poisonings, a description of the toxidrome including pharmacokinetics, clinical presentation, an overview of treatment, and the role and application of dialysis is outlined. Inhibition of alcohol dehydrogenase to prevent the formation of toxic metabolites in methanol and ethylene glycol is discussed in detail, including the use of fomepizole and ethanol to complement and in some cases prevent the need for hemodialysis. Hemodialysis has been attempted to treat many poisonings, often without success. A description of EXTRIP (Extracorporeal Treatments in Poisoning), a multidisciplinary project examining the evidence for extracorporeal treatments in poisoning, is also described. Recommendations for poisoning with acetaminophen, baclofen, barbiturates, carbamazepine, digoxin, metformin, phenytoin, thallium, theophylline, tricyclic antidepressants, and valproic acid are provided in a comprehensive table.

PMID: 32146996 [https://www.ncbi.nlm.nih.gov/pubmed/?term=32146996]

Status: Embase

Author NameID: Harbord, Nikolas; ORCID: https://orcid.org/0000-0002-4165-8090

Institution: (Harbord) Department of Medicine/Nephrology, Mount Sinai Beth Israel/Icahn School of Medicine, New York, NY, United States

Publisher: W.B. Saunders

Year of Publication: 2020

Link to the Ovid Full Text or citation:
Click here for full text options

25.

Design and evaluation of a poly(Lactide-co-glycolide)-based in situ film-forming system for topical delivery of trolamine salicylate.

Kim Y., Beck-Broichsitter M., Banga A.K.

Embase
Pharmaceutics. 11(8) (no pagination), 2019. Article Number: 409. Date of Publication: August 2019.

[Article]

AN: 2002428686

Trolamine salicylate (TS) is a topical anti-inflammatory analgesic used to treat small joint pain. The topical route is preferred over the oral one owing to gastrointestinal side effects. In this study, a poly(lactide-co-glycolide) (PLGA)-based in situ bio-adhesive film-forming system for the transdermal delivery of TS was designed and evaluated. Therefore, varying amounts (0%, 5%, 10%, 20%, and 25% (w/w)) of PLGA (EXPANSORB DLG 50-2A, 50-5A, 50-8A, and 75-5A), ethyl 2-cyanoacrylate, poly (ethylene glycol) 400, and 1% of TS were dissolved together in acetone to form the bio-adhesive polymeric solution. In vitro drug permeation studies were performed on a vertical Franz diffusion cell and dermatomed porcine ear skin to evaluate the distinct formulations. The bio-adhesive polymeric solutions were prepared successfully and formed a thin film upon application in situ. A significantly higher amount of TS was delivered from a formulation containing 20% PLGA (45 +/- 4 microg/cm2) and compared to PLGA-free counterpart (0.6 +/- 0.2 microg/cm2). Furthermore, the addition of PLGA to the polymer film facilitated an early onset of TS delivery across dermatomed porcine skin. The optimized formulation also enhanced the delivery of TS into and across the skin.

Status: Embase

Institution: (Kim, Banga) Centre for Drug Delivery Research, Department of Pharmaceutical Sciences, College of Pharmacy, Mercer University, Atlanta, GA 30341, United States (Beck-Broichsitter) MilliporeSigma a Business of Merch KGaA, Frankfurter Strasse 250, Darmstadt 64293, Germany

Publisher: MDPI AG (Postfach, Basel CH-4005, Switzerland. E-mail: indexing@mdpi.com)

Year of Publication: 2019

Link to the Ovid Full Text or citation:
Click here for full text options

26.

Management of acute radiation dermatitis: A review of the literature and proposal for treatment algorithm.

Rosenthal A., Israilevich R., Moy R.

Embase
Journal of the American Academy of Dermatology. 81(2) (pp 558-567), 2019. Date of Publication: August 2019.

[Review]

AN: 2002142454

Radiation dermatitis is a common sequela of radiation therapy; up to 95% of patients will develop moderate-to-severe skin reactions. No criterion standard currently exists for the treatment of acute radiation-induced skin toxicity. It is therefore imperative to develop a greater understanding of management options available to allow clinicians to make informed decisions when managing radiation oncology patients. This literature review discusses the topical agents that have been studied for the treatment of acute radiation dermatitis, reviews

their mechanisms of action, and presents a treatment algorithm for clinicians managing patients experiencing radiation dermatitis.

PMID: 30802561 [https://www.ncbi.nlm.nih.gov/pubmed/?term=30802561]

Status: Embase

Institution: (Rosenthal) University of Miami Miller School of Medicine, Miami, FL, United States (Rosenthal, Israilevich, Moy) Moy-Fincher-Chipps Facial Plastics & Dermatology, Beverly Hills, CA, United States

Publisher: Mosby Inc. (E-mail: customerservice@mosby.com)

Year of Publication: 2019

Link to the Ovid Full Text or citation:
Click here for full text options

27.

Highlights and implications of the 2019 proposed rule on sunscreens by the US Food and Drug Administration.

Wang S.Q., Lim H.W.

Embase
Journal of the American Academy of Dermatology. 81(2) (pp 650-651), 2019. Date of Publication: August 2019.

[Editorial]

AN: 2002081613

PMID: 30954585 [https://www.ncbi.nlm.nih.gov/pubmed/?term=30954585]

Status: Embase

Institution: (Wang) Dermatology Service, Department of Medicine, Memorial Sloan Kettering Cancer Center, Basking Ridge, NJ, United States (Lim) Department of Dermatology, Henry Ford Hospital, Detroit, MI, United States

Publisher: Mosby Inc. (E-mail: customerservice@mosby.com)

Year of Publication: 2019

Link to the Ovid Full Text or citation:
Click here for full text options

28.

Filling in the Evidence about Sunscreen.

Califf R.M., Shinkai K.

Embase
JAMA - Journal of the American Medical Association. 321(21) (pp 2077-2079), 2019. Date of Publication: 04 Jun 2019.

[Editorial]

AN: 627537700

PMID: 31058950 [https://www.ncbi.nlm.nih.gov/pubmed/?term=31058950]

Status: Embase

Institution: (Califf) Duke Forge, Duke University School of Medicine, Durham, NC, United States (Califf) Verily Life Sciences (Alphabet), South San Francisco, CA, United States
(Shinkai) Department of Dermatology, University of California, San Francisco, 1701 Divisadero St, San Francisco, CA 94115, United States
(Shinkai) JAMA Dermatology, United States

Publisher: American Medical Association (E-mail: smcleod@itsa.ucsf.edu)

Year of Publication: 2019

Link to the Ovid Full Text or citation:
Click here for full text options

29.

Formulation, characterization and in vitro / ex vivo evaluation of trolamine salicylate - loaded transfersomes as transdermal drug delivery carriers.

Makhmalzadeh B.S., Salimi A., Nazarian A., Esfahani G.

Embase
International Journal of Pharmaceutical Sciences and Research. 9(9) (pp 3725-3731), 2018.
Date of Publication: 01 Sep 2018.

[Article]

AN: 624307623

The percutaneous delivery of salicylates to muscle and joints via the application of trolamine salicylate including transfersomes is the goal of this study and is beneficial for the treatment of inflammatory muscle, tendon and joint diseases. In this study, Trolamine salicylate permeability parameters through rat skin were evaluated with different trasfersome formulations in comparison with controls with Franz diffusion cells. Transfersomes were prepared with Solvent evaporation technique. Full factorial design was applied for the experimental design and data analysis. Ethanol / lipid ratio, percentage of sodium cholate, and homogenizer rate were considered as independent variables. On the other hand, transfersome size, drug loading, stability, drug release and skin permeability parameters were regarded as responses. The results showed that the main barrier for Trolamine salicylate permeability was the horny layer and partitioning from aqueous donor phase into the skin was rate limiting step for drug flux. Maximum flux and diffusion coefficient enhancement obtained by transfersomes no. 8 and 7 were 5.5 and 2.2 - folds, respectively. Regression analysis suggested significantly and indirect correlation between percentage of ethanol and sodium cholate with drug flux. Ethanol increased drug solubility in vehicle and so decreased drug partitioning into the skin. Sodium cholate decreased drug release and skin penetration

by stabilization of lamellar membrane. Therefore, partitioning from vehicle into skin is a rate limiting step for Trolamine salicylate permeability through rat skin which was improved by transfersomes.

Status: Embase

Institution: (Makhmalzadeh, Salimi) Nanotechnology Research Center, Faculty of Pharmacy, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran, Islamic Republic of (Makhmalzadeh, Salimi, Nazarian, Esfahani) Department of Pharmaceutics, Faculty of Pharmacy, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran, Islamic Republic of

Publisher: Society of Pharmaceutical Sciences and Research (E-mail: secretary@sperpharma.org)

Year of Publication: 2018

Link to the Ovid Full Text or citation:
Click here for full text options

30.

Sunscreens: An Update.

Mancuso J.B., Maruthi R., Wang S.Q., Lim H.W.

Embase
American Journal of Clinical Dermatology. 18(5) (pp 643-650), 2017. Date of Publication: 01 Oct 2017.

[Review]

AN: 618317081

Sunscreens have been widely used by the general public for their photoprotective properties, including prevention of photocarcinogenesis and photoaging and management of

photodermatoses. It is important to emphasize to consumers the necessity of broad-spectrum protection, with coverage of both ultraviolet A (320-400 nm) and ultraviolet B (290-320 nm) radiation. This review discusses the benefits of sunscreen, different ultraviolet filters, sunscreen regulations and controversies, the importance of broad-spectrum protection, issues of photostability and formulation, and patient education and compliance.

PMID: 28510141 [https://www.ncbi.nlm.nih.gov/pubmed/?term=28510141]

Status: Embase

Institution: (Mancuso, Lim) Department of Dermatology, Henry Ford Hospital, Detroit, MI, United States (Maruthi) Boston University School of Medicine, Boston, MA, United States (Wang) Department of Dermatology, Memorial Sloane Kettering, New York, NY, United States
(Lim) Department of Dermatology, Henry Ford Medical Center-New Center One, 3031 W. Grand Boulevard, Suite 800, Detroit, MI 48202, United States

Publisher: Springer International Publishing

Year of Publication: 2017

Link to the Ovid Full Text or citation:
Click here for full text options

31.

Arthroscopic Treatment of Ankle Arthritis.

Barp E.A., Erickson J.G., Hall J.L.

Embase
Clinics in Podiatric Medicine and Surgery. 34(4) (pp 433-444), 2017. Date of Publication: October 2017.

[Review]

AN: 617477113

Ankle arthritis can be broadly classified as primary arthritis (nontraumatic degeneration) or secondary arthritis (post-traumatic degeneration). A good understanding of the anatomic features and presentations associated with each will assist the surgeon in determining the best course of action for each patient. Many variations of both primary and secondary arthritis can be treated conservatively; however, there are many times when conservative therapy is not adequate. In these cases, ankle arthroscopy may be considered before a joint fusion or replacement. Here, the authors discuss the common types of ankle arthritis, their presentations, and treatment success with ankle arthroscopy.

PMID: 28867051 [https://www.ncbi.nlm.nih.gov/pubmed/?term=28867051]

Status: Embase

Institution: (Barp) Podiatry, The Iowa Clinic, 5950 University Avenue, West Des Moines, IA 50266, United States (Erickson) Podiatry, Boone County Hospital, 1015 Union Street, Boone, IA 50036, United States
(Hall) Podiatric Residency, UnityPoint Health-Des Moines, 1415 Woodland Avenue, Suite 100, Des Moines, IA 50309, United States

Publisher: W.B. Saunders

Year of Publication: 2017

Link to the Ovid Full Text or citation:
Click here for full text options

32.

Management of Radiation Toxicity in Head and Neck Cancers.

Siddiqui F., Movsas B.

Embase
Seminars in Radiation Oncology. 27(4) (pp 340-349), 2017. Date of Publication: October 2017.

[Review]

AN: 616712770

Head and neck cancers account for approximately 3% of all cancers in the United States with 62,000 new cases diagnosed annually. The global incidence is approximately 700,000 new cases a year. There has also been a recent increase in human papilloma virus-related oropharyngeal cancers. External beam radiation therapy (RT) is commonly used as an effective therapy for head and neck (H&N) cancers. This is used as a definitive treatment (alone or in combination with chemotherapy) or as an adjuvant treatment after surgical resection of the tumors. Because of the complex anatomy of the H&N region, several critical structures in and around the area receive radiation treatment. This includes the neural structures (brainstem, spinal cord, and brachial plexus), salivary glands, mucosa, major blood vessels, and swallowing musculature. Careful RT planning is necessary to avoid or mitigate the side effects of treatment. This review discusses some of the major acute and late side effects of RT for H&N cancers and provides evidence-based guidelines for their management. Patient-reported outcomes and quality-of-life implications are also discussed.

PMID: 28865517 [https://www.ncbi.nlm.nih.gov/pubmed/?term=28865517]

Status: Embase

Institution: (Siddiqui, Movsas) Department of Radiation Oncology, Henry Ford Health System, Detroit, MI, United States

Publisher: W.B. Saunders

Year of Publication: 2017

Link to the Ovid Full Text or citation:
Click here for full text options

33.

Ultraviolet photobiology in dermatology.

Christensen L., Suggs A., Baron E.

Embase
Advances in Experimental Medicine and Biology. 996(pp 89-104), 2017. Date of Publication: 2017.

[Chapter]

AN: 619164848

The effects of ultraviolet radiation on human skin have been studied for years, and both its harmful and therapeutic effects are well known. Exposure to UV light can lead to sunburn, immunosuppression, skin aging, and carcinogenesis, and photoprotection is strongly advocated. However, when used under controlled conditions, UV radiation can also be helpful in the diagnosis and treatment of many skin conditions.

PMID: 29124693 [https://www.ncbi.nlm.nih.gov/pubmed/?term=29124693]

Status: Embase

Institution: (Christensen, Suggs, Baron) Department of Dermatology, UH Hospitals Cleveland Medical Center/Case Western Reserve University, Cleveland, OH 44106, United States

Publisher: Springer New York LLC (E-mail: barbara.b.bertram@gsk.com)

Year of Publication: 2017

Link to the Ovid Full Text or citation:
Click here for full text options

34.

Risk assessment of tea-salicylate in cosmetic products.

Baek S.-H., Lim S.-K., Kim M.-K., Suh H.-S., Kim M.-H., Lee B.-M.

Embase
Toxicology Letters. Conference: 53rd Congress of the European Societies of Toxicology, EUROTOX 2017. Bratislava Slovakia. 280(Supplement 1) (pp S104-S105), 2017. Date of Publication: October 2017.

[Conference Abstract]

AN: 623052306

TEA-salicylate is a compound used as a UV-B blocker in sunscreen agents. It is an organic compound in the form of a salt formed between triethanolamine and salicylic acid. TEA-salicylate has been approved by FDA for use at concentrations below 12%. The Euro-pean Union has approved the use of TEA-salicylate at a maximum level of 5% as preservatives in cosmetics. Similarly, its use has been approved below 12% in countries like the US and Canada. TEA-salicylate function is not limited to sunscreen agents only. It is also added as a preservative or anti-colorant in shampoo, scalp care, moisturizing and whitening products, and other cream-type prod-ucts at levels between 0.0001% and 0.75%. TEA-salicylate is usually added into cream formulation cosmetic products that are applied to the skin, thus the main route of TEA-salicylate administration is through the skin. The no observed adverse effect level (NOAEL) was estimated to be 69 mg/kg/day, when rats were orally administered TEA-salicylate for 7 days. A risk assessment was carried out in cosmetics by no observed adverse effect level (NOAEL)/systemic exposure dosage (SED). Thus, risk for TEA-salicylate in cosmetic products was calculated to be 136 based on 69mg/kg bw/day (NOAEL)/0.504 mg/kg/day (SED). This study has shown that the margin of safety when using sunscreen agents containing TEA-salicylate at the limit of regulation of 12%, is estimated to be 136, confirming the safety of its use.

Status: CONFERENCE ABSTRACT

Institution: (Baek, Lim, Kim, Suh, Kim, Lee) College of Pharmacy, Sungkyunkwan University, Seobu-ro 2066, Jangan-Gu, Suwon, Gyeonggi-Do, South Korea

Publisher: Elsevier Ireland Ltd

Year of Publication: 2017

Link to the Ovid Full Text or citation:

Click here for full text options

35.

Are sunscreens necessary in Hong Kong?.

Rademaker M.

Embase
Hong Kong Journal of Dermatology and Venereology. 24(2) (pp 70-76), 2016. Date of Publication: Summer 2016.

[Review]

AN: 611183800

Despite the relatively low-risk of skin cancer in Hong Kong (latitude 22degreeN), photo-protection remains an important health strategy to reduce photoaging and photo-immunosuppression. UVA, UVB and infrared wavelengths damage the skin through a variety of cellular and biochemical mechanisms. These can largely be mitigated by appropriate photoprotection: 1) minimising UV exposure, particular during summertime from 10.00 to 14.00 hours, 2) wearing appropriate clothing, hats and sunglasses, and 3) the effective use of sunscreens. A broad spectrum SPF50+ sunscreen should be applied daily, 30 minutes before going outdoors and re-applied immediately before going outside. The risk of vitamin D deficiency is not significantly increased with real-life sunscreen use.

Status: Embase

Institution: (Rademaker) Department of Dermatology, Waikato Hospital, Hamilton, New Zealand

Publisher: Medcom Limited (18 Cheung Lee Street, Chaiwan, Hong Kong)

Year of Publication: 2016

Link to the Ovid Full Text or citation:
Click here for full text options

36.

Sun lotion chemicals as endocrine disruptors.

Maipas S., Nicolopoulou-Stamati P.

Embase
Hormones. 14(1) (pp 32-46), 2015. Date of Publication: January 2015.

[Review]

AN: 603788936

Ultraviolet solar radiation is a well-known environmental health risk factor and the use of sun lotions is encouraged to achieve protection mainly from skin cancer. Sun lotions are cosmetic commercial products that combine active and inactive ingredients and many of these are associated with health problems, including allergic reactions and endocrine disorders. This review focuses on their ability to cause endocrine and reproductive impairments, with emphasis laid on the active ingredients (common and less common UV filters). In vitro and in vivo studies have demonstrated their ability to show oestrogenic/anti-oestrogenic and androgenic/ anti-androgenic activity. Many ingredients affect the oestrous cycle, spermatogenesis, sexual behaviour, fertility and other reproductive parameters in experimental animals. Their presence in aquatic environments may reveal a new emerging environmental hazard.

PMID: 25885102 [https://www.ncbi.nlm.nih.gov/pubmed/?term=25885102]

Status: Embase

Institution: (Maipas, Nicolopoulou-Stamati) National and Kapodistrian University of Athens, School of Medicine, Department of Pathology and Cytology Unit, 1stPathology Laboratory, Athens, Greece

Publisher: Hellenic Endocrine Society

Year of Publication: 2015

Link to the Ovid Full Text or citation:
Click here for full text options

37.

Sunscreen in the spotlight: A comprehensive review of over-the-counter SPF drug products for sun protection.

Thomas J., Julian E.

Embase
Osteopathic Family Physician. 7(4) (pp 13-17), 2015. Date of Publication: July-August 2015.

[Review]

AN: 623189425

In 2012, the Food and Drug Administration revised their guidelines on sunscreen in an attempt to cease the misleading and unsubstantiated claims commonly published on sunscreen product labels. Skin cancer is the most frequently diagnosed form of cancer in the United States with cases of skin cancer increasing worldwide. Despite these statistics, misconceptions among both consumer patients and health care practitioners, regarding sun protection factor, ultraviolet radiation, sunscreen efficacy, and application remain prevalent. For these reasons, it is imperative that practitioners have a fundamental understanding of sunscreen formularies in order to provide evidence based skin cancer prevention recommendations to their patients. This article aims at providing practitioners with a simplified yet comprehensive review of over-the-counter sunscreen drug products and the most recent FDA sunscreen monograph.

Status: Embase

Institution: (Thomas) Nova Southeastern University College of Osteopathic Medicine, Dermatology Department, United States (Julian) Nova Southeastern University College of Osteopathic Medicine, United States

Publisher: American College of Osteopathic Family Physicians (E-mail: belindab@acofp.org)

Year of Publication: 2015

Link to the Ovid Full Text or citation:
Click here for full text options

38.

Pediatric sunscreen and sun safety guidelines.

Julian E., Palestro A.M., Thomas J.A.

Embase
Clinical Pediatrics. 54(12) (pp 1133-1140), 2015. Date of Publication: 11 Oct 2015.

[Note]

AN: 605979096

PMID: 26130395 [https://www.ncbi.nlm.nih.gov/pubmed/?term=26130395]

Status: Embase

Institution: (Julian, Palestro, Thomas) Dermatology/Surgery Department, Nova Southeastern University, 3200 South University Drive, Fort Lauderdale, FL 33328, United States

Publisher: SAGE Publications Inc. (E-mail: claims@sagepub.com)

Year of Publication: 2015

Link to the Ovid Full Text or citation:
Click here for full text options

39.

Sunscreens.

Neider S.

Embase
Journal of the Dermatology Nurses' Association. 6(2) (pp 72-73), 2014. Date of Publication: March-April 2014.

[Article]

AN: 373068356

The purpose of this article is to present a brief overview on sunscreen and is not intended to be a full review. Statistical information on skin cancer is presented along with an overview of skin protective measures in addition to sunscreen. A brief description of the definition of ultraviolet (UV) radiation is reviewed and includes the basic differences between UVA and UVB. Chemical blockers versus physical blockers are explained and include a table listing of 17 active ingredients approved by the United States Food & Drug Administration. The table also differentiates physical and chemical blockers and which UV rays each type of blocker helps to protect against. A review of the Food & Drug Administration's guidelines regarding sunscreen is discussed to include the two key factors in sunscreen labeling. Finally, proper usage and patient information regarding sunscreen application are reviewed. © 2014 Dermatology Nurses' Association.

Status: Embase

Institution: (Neider) Center for SurgicalDermatology, 8704 Seabright, Powell, OH 43065, United States

Publisher: Lippincott Williams and Wilkins

Year of Publication: 2014

40.

Sunscreens in the United States: Current status and future outlook.

Jou P.C., Tomecki K.J.

Embase
Advances in Experimental Medicine and Biology. 810(pp 464-484), 2014. Date of Publication: 2014.

[Chapter]

AN: 615954185

Incidence rates of nonmelanoma skin cancer and melanoma has been on the rise in the United States for the past 20 years. UV radiation (UVR) exposure remains the most preventable environmental risk factor for these cancers. Aside from sun avoidance, sunscreens remain our best protection. UVR directly damages DNA and cause indirect cellular damage through the creation of reactive oxygen species, the sum of which leads to cutaneous immunosuppression and a tumorigenic milieu. The current generation of sunscreens protect from UVR through two main mechanisms: absorption and deflection. In the US, new Food and Drug Association rules require sunscreen manufacturers to evaluate their products not only on sun protection factor but also on broad spectrum UVA protection by the end of 2013. New labeling requirements will also be instituted. The American Academy of Dermatology and the American Academy of Pediatrics have provided specific recommendations for proper sun protection and sunscreen usage. Plant polyphenols such as those isolated from green tea, pomegranate, and grape seed remain an interesting avenue of research as additives to sunscreens or stand-alone products that appear to modulate the immunosuppressive effects of UVR on the skin. Additionally, although UVR induces endogenous cutaneous production of vitamin D, its damaging effects overshadow this positive benefit, especially in light of the ease of achieving recommended amounts of vitamin D through diet and supplementation.

PMID: 25207382 [https://www.ncbi.nlm.nih.gov/pubmed/?term=25207382]

Status: Embase

Institution: (Jou) Hennepin County Medical Center, Minneapolis, MN, United States
(Tomecki) Dermatology and Plastic Surgery Institute, The Cleveland Clinic, Cleveland, OH, United States

Publisher: Springer New York LLC (E-mail: barbara.b.bertram@gsk.com)

Year of Publication: 2014

41.

Percutaneous absorption of salicylic acid after administration of trolamine salicylate cream in rats with transcutol and eucalyptus oil pre-treated skin.

Sajjadi P., Khodayar M.J., Makhmalzadeh B.S., Rezaee S.

Embase
Advanced Pharmaceutical Bulletin. 3(2) (pp 295-301), 2013. Date of Publication: 2013.

[Article]

AN: 370047942

Purpose: This study was conducted to assess the effect of skin pre-treatment with Transcutol and eucalyptus oil on systemic absorption of topical trolamine salicylate in rat.
Method(s): Pharmacokinetic parameters of salicylic acid following administration of trolamine salicylate on rat skin pre-treated with either Transcutol or eucalyptus oil were determined using both non-compartmental and non-linear mixed effect modeling approaches and compared with those of control group.
Result(s): Median (% of interquartile range/median) of salicylic acid AUC0-8hr (ng/mL/hr) values in Transcutol or eucalyptus oil treated rats were 2522(139%) and 58976(141%), respectively as compared to the 3023(327%) of the control group. Skin pre-treatment with eucalyptus oil could significantly decrease extravascular volume of distribution (V/F) and elimination rate constant (k) of salicylic acid.

Conclusion(s): Unlike Transcutol, eucalyptus oil lead to enhanced transdermal absorption of trolamine salicylate through rat skin. © 2013 by Tabriz University of Medical Sciences.

Status: Embase

Institution: (Sajjadi) Nanotechnology Research Center, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran, Islamic Republic of (Khodayar) Department of Pharmacology and Toxicology, School of Pharmacy, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran, Islamic Republic of
(Makhmalzadeh, Rezaee) Nanotechnology Research Center, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran, Islamic Republic of

Publisher: Tabriz University of Medical Sciences (Daneshgah St, Tabriz 5166614713, Iran, Islamic Republic of. E-mail: joddd@tbzmed.ac.ir)

Year of Publication: 2013

Link to the Ovid Full Text or citation:
Click here for full text options

42.

Topical agent therapy for prevention and treatment of radiodermatitis: A meta-analysis.

Zhang Y., Zhang S., Shao X.

Embase
Supportive Care in Cancer. 21(4) (pp 1025-1031), 2013. Date of Publication: April 2013.

[Article]

AN: 369247232

Background: Radiodermatitis (RD) is a common side effect during radiotherapy. Various topical agents have been tried to be applied on RD. However, the efficiency of topical agents applied on radiotherapy is still uncertain.

Objective(s): This study aims to assess the efficiency of the topical agents in the prevention and treatment of RD.
Method(s): The Cochrane Central Register of Controlled Trials, Pubmed, and Medline were searched for relevant reports. Quantitative analysis was carried out to evaluate the efficiency of topical agents in the prevention and treatment of RD.
Result(s): Twenty reports involving 3,098 patients were included: 2,406 patients for prophylactic trials and 692 for treatment trials, respectively. For prophylactic trials, primary meta-analysis indicated that using topical agents could not reduce the incidence of grade 2 and higher RD (P=0.128, RR=0.90, 95 % CI=0.78-1.03) with a high heterogeneity (P=0.000, I 2=71.5 %). In subgroup analyses, heterogeneity disappeared by excluding reports with low Jadad score (<=3) (P=0.292, I 2=15.2 %), and still no significant difference was found between the topical agent group and control group (P=0.625, RR=0.98, 95 % CI=0.89-1.07). In addition, for treatment trials, topical agents failed to increase the incidence of wound healing (P=0.784, RR=1.01, 95 % CI=0.92-1.12) with a high heterogeneity (P=0.067, I 2=51.5 %).
Conclusion(s): Topical agents could not prevent or treat RD effectively. New type of agents should be developed to improve the efficiency based on the pathophysiology of RD. © 2012 Springer-Verlag Berlin Heidelberg.

PMID: 23064885 [https://www.ncbi.nlm.nih.gov/pubmed/?term=23064885]

Status: Embase

Institution: (Zhang, Zhang, Shao) Department of VIP Ward, Zhejiang University, Second Affiliated Hospital, Hangzhou 310000, China

Publisher: Springer Verlag (Tiergartenstrasse 17, Heidelberg D-69121, Germany)

Year of Publication: 2013

Link to the Ovid Full Text or citation:
Click here for full text options

43.

The Effect of Sunscreen on Melanoma Risk.

Mulliken J.S., Russak J.E., Rigel D.S.

Embase
Dermatologic Clinics. 30(3) (pp 369-376), 2012. Date of Publication: July 2012.

[Review]

AN: 365252342

Total cumulative sun exposure is associated with the development of squamous cell and basal cell cancers, whereas intense intermittent sun exposure is associated with the development of melanoma. Exposure to UV radiation is the only known modifiable cause of melanoma, but the role of sunscreen in melanoma prevention remains somewhat controversial. This article discusses how UV radiation contributes to the pathogenesis of melanoma, how sunscreen modulates the action of UV radiation on the skin, and the effect of sunscreen on the risk of developing melanoma. A review of available sunscreen agents and their sun-protective properties is also included. © 2012 Elsevier Inc.

PMID: 22800545 [https://www.ncbi.nlm.nih.gov/pubmed/?term=22800545]

Status: Embase

Institution: (Mulliken) New York University School of Medicine, 550 First Avenue, New York, NY 10016, United States (Russak) Department of Dermatology, Mt. Sinai School of Medicine, One Gustave L. Levy Place, New York, NY 10029-6574, United States (Rigel) Department of Dermatology, New York University School of Medicine, 550 First Avenue, New York, NY 10016, United States

Publisher: W.B. Saunders (Independence Square West, Philadelphia PA 19106-3399, United States)

Year of Publication: 2012

Link to the Ovid Full Text or citation:
Click here for full text options

44.

Shining the light on sunscreen.

Hellwig T.R., Gripentrog E.M., Templeton K.S.

Embase
U.S. Pharmacist. 37(4) (pp 36-39), 2012. Date of Publication: April 2012.

[Article]

AN: 364680826

Status: Embase

Institution: (Hellwig) Pharmacy Practice South Dakota State University College of Pharmacy, Clinical Pharmacist, Sanford USD Medical Center, Sioux Falls, SD, United States (Gripentrog, Templeton) State University College of Pharmacy, Pharmacy Intern, Sanford USD Medical Center, Sioux Falls, SD, United States

Publisher: Jobson Publishing Corporation (100 Avenue of the Americas, New York NY 10013-1678, United States)

Year of Publication: 2012

Link to the Ovid Full Text or citation:
Click here for full text options

45.

Topical photoprotection in childhood and adolescence.

Criado P., De Melo J.N., De Oliveira Z.N.P.

Embase
Jornal de Pediatria. 88(3) (pp 203-210), 2012. Date of Publication: May-June 2012.

[Review]

AN: 365320076

Objective: Exposure to sunlight in childhood is often more intense than in adults. Literature data unequivocally show the association between this social behavior and the risk for developing malignant melanoma and non-melanoma skin cancer, even in adulthood. Furthermore, skin photoaging begins already in childhood through inadequate sun exposure. This review aims to guide pediatricians on appropriate measures of topical photoprotection in children and adolescents, which will positively change the future of these patients. Sources: A review of the literature indexed in MEDLINE/PubMed between the years 1999 and 2012 on photoprotection in childhood was conducted. The most relevant review articles on photoprotection in children and adolescents, photoprotection and vitamin D in neonatal phototherapy and impact on skin cancer, artificial tanning and skin cancer were selected as sources. Summary of the findings: Children and adolescents should adopt appropriate measures of photoprotection in order to decrease the risk of melanoma and non-melanoma skin cancer.
Conclusion(s): There are published data that support the association between sun exposure habits and safe use of topical sunscreens in children and adolescents on the one hand and a reduced occurrence of skin cancer on the other. Copyright © by Sociedade Brasileira de Pediatria.

PMID: 22717610 [https://www.ncbi.nlm.nih.gov/pubmed/?term=22717610]

Status: Embase

Institution: (Criado, De Melo) Universidade de Sao Paulo (USP), Sao Paulo, SP, Brazil
(Criado) Divisao de Dermatologia, Hospital das Clinicas da Faculdade de Medicina da Universidade de Sao Paulo (HC-FMUSP), Sao Paulo, SP, Brazil
(De Melo) Divisao de Dermatologia, Ambulatorio de Dermatologia Pediatrica, HC-FMUSP, Sao Paulo, SP, Brazil
(De Oliveira) Faculdade de Medicina, USP, Sao Paulo, SP, Brazil
(De Oliveira) Ambulatorio de Dermatologia Pediatrica, HC-FMUSP, Sao Paulo, SP, Brazil

Publisher: Sociedade Brasileira de Pediatria (Av. Carlos Gomes, 328/ cj. 305 Bela Vista, Porto Alegre, Brazil)

Year of Publication: 2012

46.

Convective transport of highly plasma protein bound drugs facilitates direct penetration into deep tissues after topical application.

Dancik Y., Anissimov Y.G., Jepps O.G., Roberts M.S.

Embase
British Journal of Clinical Pharmacology. 73(4) (pp 564-578), 2012. Date of Publication: April 2012.

[Article]

AN: 364435168

AIMS To relate the varying dermal, subcutaneous and muscle microdialysate concentrations found in man after topical application to the nature of the drug applied and to the underlying physiology. METHODS We developed a physiologically based pharmacokinetic model in which transport to deeper tissues was determined by tissue diffusion, blood, lymphatic and intersitial flow transport and drug properties. The model was applied to interpret published human microdialysis data, estimated in vitro dermal diffusion and protein binding affinity of drugs that have been previously applied topically in vivo and measured in deep cutaneous tissues over time. RESULTS Deeper tissue microdialysis concentrations for various drugs in vivo vary widely. Here, we show that carriage by the blood to the deeper tissues below topical application sites facilitates the transport of highly plasma protein bound drugs that penetrate the skin, leading to rapid and significant concentrations in those tissues. Hence, the fractional concentration for the highly plasma protein bound diclofenac in deeper tissues is 0.79 times that in a probe 4.5mm below a superficial probe whereas the corresponding fractional concentration for the poorly protein bound nicotine is 0.02. Their corresponding estimated in vivo lag times for appearance of the drugs in the deeper probes were 1.1min for diclofenac and 30min for nicotine. CONCLUSIONS Poorly plasma protein bound drugs are mainly transported to deeper tissues after topical application by tissue diffusion whereas the transport of highly plasma protein bound drugs is additionally facilitated by convective blood,

lymphatic and interstitial transport to deep tissues.

PMID: 21999217 [https://www.ncbi.nlm.nih.gov/pubmed/?term=21999217]

Status: Embase

Institution: (Dancik, Roberts) Therapeutics Research Centre, School of Medicine, University of Queensland, Princess Alexandra Hospital, Brisbane, Australia (Dancik, Roberts) School of Pharmacy and Medical Sciences, University of South Australia, Adelaide, Australia
(Anissimov, Jepps) School of Biomolecular and Physical Sciences, Griffith University, Brisbane, Australia
(Dancik) Procter and Gamble Eurocor, Strombeek-Bever, Belgium

Publisher: Blackwell Publishing Ltd (9600 Garsington Road, Oxford OX4 2XG, United Kingdom)

Year of Publication: 2012

47.

Sunscreens: Obtaining adequate photoprotection.

Burnett M.E., Hu J.Y., Wang S.Q.

Embase
Dermatologic Therapy. 25(3) (pp 244-251), 2012. Date of Publication: May-June 2012.

[Article]

AN: 365523545

Adequate photoprotection plays a paramount role in reducing the burden of both photoaging and photocarcinogenesis. The scope of photoprotective strategies employed by the public,

from most to least effective, includes: sun avoidance, seeking shade, the use of protective clothing, and the application of sunscreen. Among these options, sunscreen use remains the strategy most frequently employed by the public - a reversal of the preferred order of photoprotection. Given this trend, it is clear why sunscreens invariably take center stage in any discussion regarding obtaining adequate photoprotection.

PMID: 22913442 [https://www.ncbi.nlm.nih.gov/pubmed/?term=22913442]

Status: Embase

Institution: (Burnett, Wang) Department of Dermatology, Memorial Sloan-Kettering Cancer Center, 160 E 53rd St., New York, NY 10022, United States (Hu) Department of Dermatology, Laser and Skin Institute, Chatham, NJ, United States

Publisher: Blackwell Publishing Inc. (350 Main Street, Malden MA 02148, United States)

Year of Publication: 2012

48.

Hot topics on UV filter ingredients.

Andreassi M., Anselmi C.

Embase
Expert Review of Dermatology. 6(5) (pp 493-499), 2011. Date of Publication: October 2011.

[Review]

AN: 362687009

The production of sunscreens is regulated by laws and lists, constantly updated on the basis of scientific information. Most advanced countries have regulatory bodies that publish and update the list of authorized substances. Inorganic filters, zinc oxide and titanium dioxide are

often used as nanostructured forms. Nanoparticles have been the subject of technological studies aimed at improving efficacy and safety. The organic ingredients are able to absorb UV radiation on a selective or broad spectrum. The latter is preferable given the role of UVA radiation in skin carcinogenesis. The organic filters may interact with epidermal proteins and induce sensitization. They can also be absorbed, causing systemic effects. In addition, some organic ingredients, such as avobenzone, may undergo photodegradation, needing special formulation requirements. © 2011 Expert Reviews Ltd.

Status: Embase

Institution: (Andreassi, Anselmi) Department of Pharmaceutical and Applied Chemistry, University of Siena, Siena, Italy

Publisher: Expert Reviews Ltd. (2 Albert Place, London N3 1QB, United Kingdom)

Year of Publication: 2011

Link to the Ovid Full Text or citation:
Click here for full text options

49.

Sunscreens.

Kaimal S., Abraham A.

Embase
Indian Journal of Dermatology, Venereology and Leprology. 77(2) (pp 238-243), 2011. Date of Publication: March-April 2011.

[Article]

AN: 361485944

PMID: 21393968 [https://www.ncbi.nlm.nih.gov/pubmed/?term=21393968]

Status: Embase

Institution: (Kaimal, Abraham) Department of Dermatology, St. John's Medical College Hospital, Bangalore - 560 034, India

Publisher: Medknow Publications and Media Pvt. Ltd (B9, Kanara Business Centre, off Link Road, Ghatkopar (E), Mumbai 400 075, India)

Year of Publication: 2011

Link to the Ovid Full Text or citation:
Click here for full text options

50.

Complications from radiotherapy for breast cancer.
Complicacoes da radioterapia no cancer de mama
Marta G.N., Hanna S.A., Martella E., da Silva J.L.F.

Embase
Sao Paulo Medical Journal. 129(2) (pp 116-117), 2011. Date of Publication: Mar. 2011.

[Letter]

AN: 361862007

PMID: 21603791 [https://www.ncbi.nlm.nih.gov/pubmed/?term=21603791]

Status: Embase

Institution: (Marta) Oncology Center, Hospital Sirio-Libanes, Sao Paulo, Brazil (Hanna) Department of Radiation Oncology, Preceptor of radiotherapy residency, Hospital Sirio-Libanes, Sao Paulo, Brazil
(Martella) Radiation therapy specialist and attending physician, Department of Radiation Oncology, Hospital Sirio-Libanes, Sao Paulo, Brazil
(da Silva) Radiation therapy specialist and coordinator, Department of Radiation Oncology, Hospital Sirio-Libanes, Sao Paulo, Brazil

Publisher: Associacao Paulista de Medicina (Av. Brig. Luiz Antonio 278 - 7o andar, Sao Paulo 01318-901, Brazil)

Year of Publication: 2011

Link to the Ovid Full Text or citation:
Click here for full text options

51.

Ultraviolet radiation protection: Current available resources in photoprotection.
Protecao a radiacao ultravioleta: Recursos disponiveis na atualidade em fotoprotecao
Balogh T.S., Velasco M.V.R., Pedriali C.A., Kaneko T.M., Baby A.R.

Embase
Anais Brasileiros de Dermatologia. 86(4) (pp 732-742), 2011. Date of Publication: July/Aug. 2011.

[Review]

AN: 362733140

Ultraviolet radiation can damage the DNA, cause immunosuppression, chemical and histological alterations in the epidermis, early photoaging, cataracts and carcinogenesis, among others. Photoprotection prevents these and other harmful effects of ultraviolet radiation. Sunscreens, protective clothing, proper accessories and safe sun exposure are essential photoprotection tools. The main forms of photoprotection are presented and discussed in this article, including sunscreens containing organic and inorganic filters, the assessment of their efficacy and current developments on the topic. © 2011 by Anais Brasileiros de Dermatologia.

PMID: 21987140 [https://www.ncbi.nlm.nih.gov/pubmed/?term=21987140]

Status: Embase

Institution: (Balogh, Velasco, Pedriali, Kaneko, Baby) University of Sao Paulo School of Pharmaceutical Sciences, (FCF - USP), Sao Paulo (SP), Brazil

Publisher: Sociedade Brasileira de Dermatologia (Av. Ipiranga 5311 sala 208, Porto Alegre/RS 90610-001, Brazil)

Year of Publication: 2011

Link to the Ovid Full Text or citation:
Click here for full text options

52.

Sunscreens: An overview and update.

Sambandan D.R., Ratner D.

Embase
Journal of the American Academy of Dermatology. 64(4) (pp 748-758), 2011. Date of Publication: April 2011.

[Review]

AN: 51259999

Sunscreens are an important aspect of photoprotection. Their efficacy in reducing photocarcinogenesis and photoaging is widely documented. Although there are concerns regarding long-term sunscreen safety, the advantages of sunscreen use are far more compelling. In addition, novel technologies and ultraviolet filters are improving the aesthetics and efficacy of modern products. © 2010 by the American Academy of Dermatology, Inc.

PMID: 21292345 [https://www.ncbi.nlm.nih.gov/pubmed/?term=21292345]

Status: Embase

Institution: (Sambandan) Columbia University College of Physicians and Surgeons, 630 West 168th St, Box 120, New York, NY 10032, United States (Ratner) Department of Dermatology, Columbia University Medical Center, New York, NY, United States

Publisher: Mosby Inc. (11830 Westline Industrial Drive, St. Louis MO 63146, United States)

Year of Publication: 2011

Link to the Ovid Full Text or citation:
Click here for full text options

53.

Prophylaxis and management of acute radiation-induced skin reactions: A systematic review of the literature.

Salvo N., Barnes E., van Draanen J., Stacey E., Mitera G., Breen D., Giotis A., Czarnota G., Pang J., de Angelis C.

Embase
Current Oncology. 17(4) (pp 94-112), 2010. Date of Publication: 2010.

[Erratum]

AN: 359938694

Radiation therapy is a common treatment for cancer patients. One of the most common side effects of radiation is acute skin reaction (radiation dermatitis) that ranges from a mild rash to severe ulceration. Approximately 85% of patients treated with radiation therapy will experience a moderate-to-severe skin reaction. Acute radiation-induced skin reactions often lead to itching and pain, delays in treatment, and diminished aesthetic appearance-and subsequently to a decrease in quality of life. Surveys have demonstrated that a wide variety of topical, oral, and intravenous agents are used to prevent or to treat radiation-induced skin reactions. We conducted a literature review to identify trials that investigated products for the prophylaxis and management of acute radiation dermatitis. Thirty-nine studies met the pre-defined criteria, with thirty-three being categorized as prophylactic trials and six as management trials. For objective evaluation of skin reactions, the Radiation Therapy Oncology Group criteria and the U.S. National Cancer Institute Common Toxicity Criteria were the most commonly used tools (65% of the studies). Topical corticosteroid agents were found to significantly reduce the severity of skin reactions; however, the trials of corticosteroids evaluated various agents, and no clear indication about a preferred corticosteroid has

emerged. Amifostine and oral enzymes were somewhat effective in preventing radiation-induced skin reactions in phase ii and phase iii trials respectively; further large randomized controlled trials should be undertaken to better investigate those products. Biafine cream (Ortho-McNeil Pharmaceuticals, Titusville, NJ, U.S.A.) was found not to be superior to standard regimes in the prevention of radiation-induced skin reactions (n = 6). In conclusion, the evidence is insufficient to support the use of a particular agent for the prevention and management of acute radiation-induced skin reactions. Future trials should focus on comparing agents and approaches that, in phase i and ii trials, suggest efficacy. These future phase iii randomized controlled trials must clearly distinguish between preventive and management strategies for radiation-induced dermatitis. Only then can evidence-based guidelines be developed, with the hope of standardizing the approach across centres and of improving the prevention and management of radiation-induced dermatitis.

Status: Embase

Institution: (Salvo, van Draanen, Stacey, Giotis, Czarnota) Department of Pharmacy, Edmond Odette Cancer Centre, Sunnybrook Health Sciences Centre, Toronto, ON, Canada (Barnes, Mitera, Breen, Pang, de Angelis) Department of Radiation Oncology, Edmond Odette Cancer Centre, Sunnybrook Health Sciences Centre, Toronto, ON, Canada

Publisher: Multimed Inc.

Year of Publication: 2010

Link to the Ovid Full Text or citation:
Click here for full text options

54.

Topical rubefacients for acute and chronic pain in adults.

Matthews P., Derry S., Moore R.A., McQuay H.J., Moore M.

Embase
Cochrane Database of Systematic Reviews. (3) (no pagination), 2009. Article Number: CD007403. Date of Publication: 2009.

[Review]

AN: 355236796

Background: Rubefacients (containing salicylates or nicotinamides) cause irritation of the skin, and are believed to relieve various musculo-skeletal pains. They are available on prescription, and are common components in over-the-counter remedies. A non-Cochrane review in 2004 found limited evidence for efficacy.
Objective(s): To review current evidence for efficacy and safety of topically applied rubefacients in acute and chronic painful musculoskeletal conditions in adults. Search strategy: Cochrane CENTRAL, MEDLINE, EMBASE, the Oxford Pain Relief Database, and reference lists of articles were searched; last search December 2008.

Selection Criteria: Randomised, double blind, placebo or active controlled clinical trials of topical rubefacient for musculoskeletal pain in adults, with at least 10 participants per treatment arm, and reporting outcomes at close to 7 (minimum 3, maximum 10) days for acute conditions and 14 (minimum 7) days or longer for chronic conditions.

Data Collection and Analysis: Two review authors independently assessed trials for inclusion and quality, and extracted data. Relative benefit or risk and number needed to treat to benefit or harm (NNT or NNH) were calculated with 95% confidence intervals (CI). Acute and chronic conditions were analysed separately.
Main Result(s): Six placebo and one active controlled studies (560 and 137 participants) in acute pain, and seven placebo and two active controlled studies (489 and 90 participants) in chronic pain were included. All used topical salicylates. The evidence in acute conditions was not robust; using only better quality, valid studies, there was no difference between topical rubefacient and topical control, though overall, including lower quality studies, the NNT for clinical success compared with placebo was 3.2 (95% CI: 2.4 to 4.9). In chronic conditions the NNT was 6.2 (95% CI: 4.0 to 13) compared with topical placebo. Adverse events and withdrawals occurred more often with rubefacients than placebo, but analyses were sensitive to inclusion of individual studies, so not robust. There were insufficient data to draw conclusions against active controls. Authors' conclusions: The evidence does not support the use of topical rubefacients containing salicylates for acute injuries, and suggests that in chronic conditions their efficacy compares poorly with topical non-steroidal antiinflammatory drugs (NSAIDs). Topical salicylates seem to be relatively well tolerated in the short-term, based on limited data. There is no evidence at all for topical rubefacients with other components.

PMID: 19588430 [https://www.ncbi.nlm.nih.gov/pubmed/?term=19588430]

Status: Embase

Institution: (Derry, Moore, McQuay, Moore) Pain Research and Nuffield Department of Anaesthetics, University of Oxford, John Radcliffe Hospital, Oxford, Oxfordshire, OX3 9DU, United Kingdom (Matthews) St. Hugh's College, University of Oxford, Oxford, United Kingdom

Publisher: John Wiley and Sons Ltd (Southern Gate, Chichester, West Sussex PO19 8SQ, United Kingdom)

Year of Publication: 2009

Link to the Ovid Full Text or citation:
Click here for full text options

55.

Trolamine over-the-counter: Better emollients are available.

Anonymous

Embase
Prescrire International. 19(106) (pp 64), 2010. Date of Publication: April 2010.

[Short Survey]

AN: 358605651

PMID: 20568679 [https://www.ncbi.nlm.nih.gov/pubmed/?term=20568679]

Status: Embase

Publisher: Association Mieux Prescrire (83, boulevard Voltaire, Paris 75011, France)

Year of Publication: 2010

Link to the Ovid Full Text or citation:
Click here for full text options

56.

Homeopathic medicines for adverse effects of cancer treatments.

Kassab S., Cummings M., Berkovitz S., Van Haselen R., Fisher P.

Embase
Cochrane Database of Systematic Reviews. (2) (no pagination), 2009. Article Number: CD004845. Date of Publication: 2009.

[Review]

AN: 355267407

Background: Homeopathic medicines are used by patients with cancer, often alongside conventional treatment. Cancer treatments can cause considerable morbidity and one of the reasons patients use homeopathic medicines is to help with adverse effects.
Objective(s): Evaluate effectiveness and safety of homeopathic medicines used to prevent or treat adverse effects of cancer treatments. Search strategy: The following were searched up to November 2008: Cochrane PaPaS Trials Register; Cochrane Central Register of Controlled Trials (CENTRAL); MEDLINE; EMBASE; CINAHL; BNI; CancerLIT; AMED; CISCOM; Hom-Inform; SIGLE; National Research Register; Zetoc; www.controlled-trials.com; http://clinicaltrials.gov; Liga Medicorum Homeopathica Internationalis (LMHI, Liga) conference proceedings; reference lists of relevant studies were checked; and homeopathic manufacturers, leading researchers and practitioners were contacted.

Selection Criteria: Randomised controlled trials (RCTs) of homeopathic medicines in participants with a clinical or histological diagnosis of cancer where the intervention was aimed at preventing or treating symptoms associated with cancer treatments. All age groups, and all stages of disease were included.

Data Collection and Analysis: Two review authors independently assessed studies for inclusion and two review authors extracted data. Three review authors independently assessed trial quality using the Delphi List and the Cochrane Collaboration's tool for assessing risk of bias. Disagreements were resolved by consensus. Where available, data were extracted for analysis.
Main Result(s): Eight controlled trials (seven placebo controlled and one trial against an active treatment) with a total of 664 participants met the inclusion criteria. Three studied adverse effects of radiotherapy, three studied adverse effects of chemotherapy and two studied menopausal symptoms associated with breast cancer treatment. Two studies with low risk of bias demonstrated benefit: one with 254 participants demonstrated superiority of topical calendula over trolamine (a topical agent not containing corticosteroids) for prevention of radiotherapy-induced dermatitis, and another with 32 participants demonstrated superiority of Traumeel S (a proprietary complex homeopathic medicine) over placebo as a mouthwash for chemotherapy-induced stomatitis. Two other studies reported positive results, although the risk of bias was unclear, and four further studies reported negative results. No serious adverse effects or interactions were reported attributable to the homeopathic medicines used. Authors' conclusions: This review found preliminary data in support of the efficacy of topical calendula for prophylaxis of acute dermatitis during radiotherapy and Traumeel S mouthwash in the treatment of chemotherapy-induced stomatitis. These trials need replicating. There is no convincing evidence for the efficacy of homeopathic medicines for other adverse effects of cancer treatments. Further research is required.

PMID: 19370613 [https://www.ncbi.nlm.nih.gov/pubmed/?term=19370613]

Status: Embase

Institution: (Kassab, Berkovitz, Fisher) Royal London Homoeopathic Hospital, 60 Great Ormond Street, London, WC1N 3HR, United Kingdom (Cummings) British Medical Acupuncture Society, London, United Kingdom
(Van Haselen) INTMEDI, Surrey, United Kingdom

Publisher: John Wiley and Sons Ltd (Southern Gate, Chichester, West Sussex PO19 8SQ, United Kingdom)

Clinical Trial Number: https://clinicaltrials.gov/show/NCT00080873

Year of Publication: 2009

Link to the Ovid Full Text or citation:
Click here for full text options

57.

Phytotherapeutics: An evaluation of the potential of 1000 plants.

Cravotto G., Boffa L., Genzini L., Garella D.

Embase
Journal of Clinical Pharmacy and Therapeutics. 35(1) (pp 11-48), 2010. Date of Publication: February 2010.

[Review]

AN: 358125016

Objective: The aim of this review is to evaluate and summarize the available scientific information on the commonest plant extracts marketed in Western countries. In view of the intense, ongoing search for new plant extracts with powerful anti-inflammatory activity, we paid particular attention to this topic. The aim is to provide broad coverage of as many potentially useful plants as possible and then to focus on those with the greatest therapeutic potential.
Method(s): Our bibliographic sources were the SciFinder databases: CAPLUS, MEDLINE, REGISTRY, CASREACT, CHEMLIST, CHEMCATS (update to October 2007). In order to assess the value of clinical trials, we focused a specific search on clinical investigations concerning nine plants with the most trial data, viz., Althaea officinalis, Calendula officinalis, Centella asiatica, Echinacea purpurea, Passiflora incarnata, Punica granatum, Vaccinium macrocarpon, Vaccinium myrtillus, Valeriana officinalis. This was carried out in several databases (update to June 2008): ISI Web of KnowledgeSM (ISI WoK), SciFinder (CAPLUS, MEDLINE, REGISTRY, CASREACT, CHEMLIST, CHEMCATS) and PubMed (indexed for MEDLINE).
Result(s): Our survey covers roughly a 1000 plants, although clinical trials have been published only for 156 plants supporting specific pharmacological activities and therapeutic applications. However, for about half of the plants, in vitro and in vivo studies provide some

support for therapeutic use. For one-fifth of the plants included in our search, only phytochemical studies were found. Their properties and indications were often attributed to the presence of certain compounds, but no evidence concerning the activities of the whole extracts was presented. We found that for about 12% of the plants, currently available on the Western market, no substantial studies on their properties had been published, while there was strong evidence that 1 in 200 were toxic or allergenic, so that their use ought to be discouraged or forbidden. Nine plants had considerable evidence of therapeutic effect, viz., A. officinalis, Calendula officinalis, Centella asiatica, E. purpurea, Passiflora incarnata, Punica granatum, Vaccinium macrocarpon, Vaccinium myrtillus, Valeriana officinalis.
Conclusion(s): The present review provides a baseline on the level of evidence available on many herbal preparations and should be of help to those intending to research further on these topics.

PMID: 20175810 [https://www.ncbi.nlm.nih.gov/pubmed/?term=20175810]

Status: Embase

Institution: (Cravotto, Boffa, Genzini, Garella) Dipartimento di Scienza e Tecnologia Del Farmaco, University of Turin, Via Pietro Giuria 9, 10125 Turin, Italy

Publisher: Blackwell Publishing Ltd (9600 Garsington Road, Oxford OX4 2XG, United Kingdom)

Year of Publication: 2010

58.

The effect of chemical and physical enhancers on trolamine salicylate permeation through rat skin.

Zadeh B.S.M., Hasani M.H.

Embase

Tropical Journal of Pharmaceutical Research. 9(6) (pp 541-548), 2010. Date of Publication: December 2010.

[Article]

AN: 361112622

Purpose: To achieve percutaneous delivery of trolamine salicylate to muscle and joints for the treatment of inflammatory muscle, tendon and joint diseases.
Method(s): Trolamine salicylate permeability parameters through rat skin were evaluated with and without chemical enhancers - Transcutol, eucalyptus oil, oleic acid and sodium lauryl sulfate - using the permeability cell technique.
Result(s): The main barrier for trolamine salicylate permeability was the epidermis layer of the skin. Also, partitioning from the aqueous donor phase into the skin was the rate-limiting step for drug flux. Transcutol and eucalyptus oil were the most effective enhancers as they increased flux 11-fold. Sodium lauryl sulfate disrupted the lipid structure of the skin and thus increased diffusion coefficient 3-fold. Supersaturation technique did not increase flux. Propylene glycol in cosolvent system increased drug solubility in donor phase and partitioning.
Conclusion(s): Trolamine salicylate exhibited less flux and diffusion coefficient through rat skin than salicylic acid due to its hydrophilic property. Partitioning from vehicle into skin was the rate-limiting step for trolamine salicylate permeability through rat skin. © Pharmacotherapy Group.

Status: Embase

Institution: (Zadeh, Hasani) School of Pharmacy, Jundishapour University of Medical Sciences, Ahvaz, Iran, Islamic Republic of

Publisher: Pharmacotherapy Group (Benin City 300001, Nigeria)

Year of Publication: 2010

Link to the Ovid Full Text or citation:
Click here for full text options

59.

Anti-inflammatory cream reduces skin damage induced by ionizing radiation.

Simard P.F., Bolto R.M., Tarbell N.J.

Embase
Oncologist. 14(2) (pp 197-198), 2009. Date of Publication: February 2009.

[Letter]

AN: 354431763

PMID: 19251909 [https://www.ncbi.nlm.nih.gov/pubmed/?term=19251909]

Status: Embase

Institution: (Simard, Bolto, Tarbell) Department of Radiation Oncology, Massachusetts General Hospital, Boston, MA, United States (Simard) 5223 Springlake Way, Baltimore, MD 21212, United States

Publisher: AlphaMed Press (318 Blackwell St. Suite 260, Durham NC 27701-2884, United States)

Year of Publication: 2009

Link to the Ovid Full Text or citation:
Click here for full text options

60.

Evidence-based pain management and palliative care in issue two for 2009 of the cochrane library.

Wiffen P.J.

Embase

Journal of Pain and Palliative Care Pharmacotherapy. 23(3) (pp 290-294), 2009. Date of Publication: 2009.

[Short Survey]

AN: 355725578

The Cochrane Library of Systematic Reviews is published quarterly. Issue 2 2009 contains 3826 complete reviews, 1959 protocols for reviews in production, and 9964 one-page summaries of systematic reviews published in the general medical literature. In addition, there are citations of 576,000 randomized controlled trials, and 11,500 cited papers in the Cochrane methodology register. The health technology assessment database contains 7717 citations. This edition of the Library contains 89 new reviews, of which 10 have potential relevance for practitioners in pain and palliative medicine.

PMID: 19670024 [https://www.ncbi.nlm.nih.gov/pubmed/?term=19670024]

Status: Embase

Institution: (Wiffen) Oxford Regional Pain Relief Unit, Churchill Hospital (Wiffen) Cochrane Collaboration Pain Palliative and Supportive Care Collaborative Review Group
(Wiffen) UK Cochrane Centre, Oxford, OX2 7LG, United Kingdom

Publisher: Informa Healthcare (52 Vanderbilt Ave., New York 10017, United States)

Year of Publication: 2009

Link to the Ovid Full Text or citation:
Click here for full text options

61.

Choosing pain medicine for osteoarthritis: Consumer summary guide.

Anonymous

Embase
Journal of Pain and Palliative Care Pharmacotherapy. 23(4) (pp 437-442), 2009. Date of Publication: 2009.

[Short Survey]

AN: 355750845

The Journal presents this public domain document to inform clinicians of information that the federal government provide to consumers pharmacotherapy for osteoarthritis. This consumer guide is complemented by a Clinicians Summary Guide on the same topic published by the AHRQ in March 2009. That guide also appears in this issue of the Journal. On January 10, 2007, the federal Agency for Healthcare Quality and Research (AHRQ) published a consumer summary guide on pain medications for osteoarthritis (OA), including acetaminophen, prescription, and over-the-counter nonsteroidal anti-inflammatory drugs (NSAIDs), including the COX-2 (cyclooxygenase-2)selective NSAID celecoxib, capsaicin, topical analgesic balms, opioids, and glucosamine and chondroitin. Potential risk and benefits of each drug class are described. This information is presented in a "fast facts" format on a very basic level. Relative costs are presented. The consumer guide does not address nonpharmacological interventions.

Status: Embase

Publisher: Informa Healthcare (52 Vanderbilt Ave., New York 10017, United States)

Year of Publication: 2009

Link to the Ovid Full Text or citation:
Click here for full text options

62.

Post-mastectomy radiotherapy.

Zellars R.

Embase

Clinical Advances in Hematology and Oncology. 7(8) (pp 533-543), 2009. Date of Publication: 2009.

[Review]

AN: 355371286

Between 1997 and 1999, three studies re-ignited the debate on post-mastectomy radiation therapy (PMRT). Despite 20 years of follow-up and multiple re-analyses, the results of these studies still generate vigorous debate among the learned men and women who care for breast cancer patients. In honor of the 10th anniversary of the Danish Breast Cancer Cooperative Group Post-Mastectomy trial 82c publication, the following review offers the reader a brief history of the controversies that preceded and followed these publications. Other related controversies, PMRT in the setting of neo-adjuvant chemotherapy, positive margins or T3N0 primary tumors, as well as internal mammary lymph node irradiation, are also presented. Finally, we present a brief discussion about the toxicities associated with PMRT. This review will familiarize the reader with often discussed/debated issues concerning PMRT and prepare them to enter the debate.

PMID: 19927981 [https://www.ncbi.nlm.nih.gov/pubmed/?term=19927981]

Status: Embase

Institution: (Zellars) Department of Radiation Oncology and Molecular Radiation Sciences, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University, 401 North Broadway, Baltimore, MD 21231-2410, United States

Publisher: Millennium Medical Publishing, Inc. (611 Broadway, Suite 828, New York NY 10012, United States)

Year of Publication: 2009

Link to the Ovid Full Text or citation:
Click here for full text options

63.

Extracts from The Cochrane Library: Homeopathic medicines for adverse effects of cancer treatments.

Burton M.J., Couch M.E., Rosenfeld R.M.

Embase
Otolaryngology - Head and Neck Surgery. 141(2) (pp 162-165), 2009. Date of Publication: August 2009.

[Article]

AN: 354969206

The "Cochrane Corner" is a quarterly section in the Journal that highlights systematic reviews relevant to otolaryngology-head and neck surgery, with invited commentary to aid clinical decision making. This installment features a Cochrane Review entitled "Homeopathic medicines for adverse effects of cancer treatments," which finds preliminary data to support efficacy of topical calendula for radiation-induced dermatitis and a proprietary mouthwash for chemotherapy-induced stomatitis. © 2009 American Academy of Otolaryngology-Head and Neck Surgery Foundation.

Status: Embase

Institution: (Burton) Department of Otolaryngology, University of Oxford, The Radcliffe Infirmary, Oxford, United Kingdom (Couch) Department of Otolaryngology, University of North Carolina, Chapel Hill School of Medicine, Chapel Hill, NC, United States (Rosenfeld) State University of New York at Downstate, The Long Island College Hospital, Brooklyn, NY, United States

Publisher: SAGE Publications Inc. (2455 Teller Road, Thousand Oaks CA 91320, United States)

Year of Publication: 2009

64.

Trigeminal trophic syndrome: Improvement with trolamine/sodium alginate-containing topical emulsion.

Walling H.W., Schulz K.K.

Embase
Journal of the American Academy of Dermatology. 61(1) (pp 160-161), 2009. Date of Publication: July 2009.

[Article]

AN: 354728573

PMID: 19539862 [https://www.ncbi.nlm.nih.gov/pubmed/?term=19539862]

Status: Embase

Institution: (Walling, Schulz) Town Square Dermatology, Coralville, IA, United States

Publisher: Mosby Inc. (11830 Westline Industrial Drive, St. Louis MO 63146, United States)

Year of Publication: 2009

Link to the Ovid Full Text or citation:
Click here for full text options

65.

Photoprotection.

Rai R., Srinivas C.R.

Embase
Indian Journal of Dermatology, Venereology and Leprology. 73(2) (pp 73-79), 2007. Date of Publication: 01 Mar 2007.

[Review]

AN: 46675028

The deleritious effect of ultraviolet radiation on humans has increased the need for photoprotection. Sunscreens are widely used as photo protective agents. They are divided into chemical sunscreens which absorb high-energy ultraviolet rays and physical blockers which reflect or scatter light. Effectiveness of sunscreens depends upon sun protection factor and its substantivity. Clothing is also important for sun protection and its effectiveness is measured by Ultraviolet Protection Factor. There are many other agents with photo protective properties, which range from antioxidants to plant extracts to DNA repair enzymes. Usage of wide brimmed hats and sunglasses, avoidance of solar exposure at times of peak intensity, use of cover-up garments and sunscreen lotions are effective for photo protection of the skin.

PMID: 17456910 [https://www.ncbi.nlm.nih.gov/pubmed/?term=17456910]

Status: Embase

Institution: (Rai, Srinivas) Department of Dermatology, PSG Hospitals, Peelamedu, Coimbatore, India (Srinivas) Department of Dermatology, PSG Hospitals, Coimbatore-641 004, Tamil Nadu, India

Publisher: Medknow Publications and Media Pvt. Ltd

Year of Publication: 2007

Link to the Ovid Full Text or citation:
Click here for full text options

66.

Review of the pharmaceutical properties and clinical effects of the topical NSAID formulation, diclofenac epolamine.

Rainsford K.D., Kean W.F., Ehrlich G.E.

Embase
Current Medical Research and Opinion. 24(10) (pp 2967-2992), 2008. Date of Publication: October 2008.

[Review]

AN: 352623102

Background: Topical formulations of non-steroidal antiinflammatory drugs (NSAIDs), in particular diclofenac (DI), have become popular for treating various acute and chronic painful inflammatory conditions.
Objective(s): To perform a literature review of (1) the use of topical NSAIDs; (2) the pharmaceutical, pharmacokinetic and pharmacodynamic properties of a medicated plaster (patch) containing diclofenac epolamine (DI-EP, Flector Tissugel, Flector patch*) compared with other formulations of topical NSAIDs; and (3) evaluation of the clinical findings from studies with this novel DI-EP patch.
Outcome(s): (1) Pharmacokinetic studies involved determination of DI from DI-EP and separately epolamine (EP) and the epoxide metabolite (N-oxide-EP) in laboratory animals and humans; the latter being the major metabolite in humans. About 2% of DI is absorbed by the skin in humans and is excreted in the urine. Maximum plasma concentrations of 17.4 ng/mL DI are reached at 5.4 hours (approximate steady state conditions); the plasma elimination half-time (ty2) being 26.4 hours. Low systemic levels of DI and EP are produced from DI-EP. Pronounced accumulation of DI occurs in the muscle layers and in synovial fluids of arthritic patients; (2) No significant toxicity occurs from EP nor N-oxide-EP, while that of oral DI-EP was similar to that from DI; and (3) In acute musculoskeletal conditions (sprains, tendonitis and sports injuries) and osteoarthritis DI-EP patches control pain and signs of joint or physical injury compared with placebo controls by 3-5 days with almost complete pain relief at 14 days. DI-EP was shown to have equivalent therapeutic effect to another DI diethylammonium gel formulation (Voltaren Emulgel+). There were no reports of serious adverse events in the gastro-intestinal (GI) tract, kidneys or liver from DI-EP. Mild GI symptoms and skin reactions occur in 2 and 10% of patients, respectively.
Conclusion(s): The patch delivery of DI in DI-EP affords controlled delivery of the active drug in contrast to that from application of gels or ointments of NSAIDs. © 2008 Informa UK Ltd.

PMID: 18814824 [https://www.ncbi.nlm.nih.gov/pubmed/?term=18814824]

Status: Embase

Institution: (Rainsford) Biomedical Research Centre, Faculty of Health and Wellbeing, Sheffield Hallam University, Howard Street, Sheffield S1 1WB, United Kingdom (Kean) Department of Medicine, Faculty of Health Sciences, McMaster University, Hamilton, ON, Canada
(Ehrlich) Section of Rheumatology, Department of Medicine, The University of Pennsylvania Health Sciences Center, Philadelphia, PA, United States

Publisher: Informa Healthcare (69-77 Paul Street, London EC2A 4LQ, United Kingdom)

Year of Publication: 2008

67.

Current sunscreen issues: 2007 Food and Drug Administration sunscreen labelling recommendations and combination sunscreen/insect repellent products.

Hexsel C.L., Bangert S.D., Hebert A.A., Lim H.W.

Embase
Journal of the American Academy of Dermatology. 59(2) (pp 316-323), 2008. Date of Publication: August 2008.

[Review]

AN: 50146943

The Food and Drug Administration (FDA) regulates sunscreens as over-the-counter drugs. This article describes sunscreen actives available in the United States, new developments available elsewhere, and the amendment to the FDA 1999 sunscreen monograph, released on August 27, 2007, which proposes a new grading system for ultraviolet B protection, a cap of the sunburn protection factor to 50+, and a 4-star grading of ultraviolet A protection. In addition, current data on combination sunscreen and insect repellent products are discussed. Application of a combination product too frequently poses the risk of insect repellent toxicity, whereas application too infrequently invites photodamage. It may be prudent to follow the

same approach of our Canadian colleagues of discontinuing combination products until more investigations are available.

PMID: 18485529 [https://www.ncbi.nlm.nih.gov/pubmed/?term=18485529]

Status: Embase

Institution: (Hexsel, Lim) Department of Dermatology, Henry Ford Hospital, Detroit, MI, United States (Bangert, Hebert) Department of Dermatology, University of Texas, Houston, TX, United States
(Bangert, Hebert) Department of Pediatrics, University of Texas, Houston, TX, United States

Publisher: Mosby Inc. (11830 Westline Industrial Drive, St. Louis MO 63146, United States)

Year of Publication: 2008

Link to the Ovid Full Text or citation:
Click here for full text options

68.

Symptom management in premenopausal patients with breast cancer.

Loprinzi C.L., Wolf S.L., Barton D.L., Laack N.N.

Embase
The Lancet Oncology. 9(10) (pp 993-1001), 2008. Date of Publication: October 2008.

[Review]

AN: 352432258

Women with breast cancer have many adverse symptoms, of which some are specific to premenopausal patients. Management of these common symptoms include non-hormonal drugs, such as antidepressants and antiseizure compounds to alleviate hot flushes. Non-oestrogenic vaginal lubricants seem to moderately decrease occurrence of vaginal dryness and dyspareunia. Transdermal testosterone alone has not been shown to improve libido in

these women. Options for fertility preservation include cryopreservation of embryos or oocytes before chemotherapy. Exercise is the one evidenced-based intervention shown to positively affect cancer-related fatigue. However, effective prevention and treatments for peripheral neuropathy and paclitaxel acute pain syndrome remain elusive. Weight-bearing exercise helps to maintain bone strength with adequate intake of calcium and vitamin D. Use of bisphosphonates in women taking aromatase inhibitors (combined with ovarian suppression in premenopausal women) to prevent bone fractures has not been substantiated, although it should be considered in women with osteoporosis. No specific drug has been shown to prevent radiation-induced dermatitis alone. Although some effective treatments can counteract symptoms related to cancer or treatments, research is needed to expand evidence-based care in premenopausal survivors of breast cancer.

PMID: 19071256 [https://www.ncbi.nlm.nih.gov/pubmed/?term=19071256]

Status: Embase

Institution: (Loprinzi, Wolf, Barton) Department of Medical Oncology, Mayo Clinic, Rochester, MN, United States (Laack) Department of Radiation Oncology, Mayo Clinic, Rochester, MN, United States

Publisher: Lancet Publishing Group (Elsevier, The Boulevard, Langford, Kidlington, Oxford OX5 1GB, United Kingdom)

Year of Publication: 2008

Link to the Ovid Full Text or citation:
Click here for full text options

69.

FDA's proposed ruling on sunscreen protection products.

Sheth N.U.

Embase
U.S. Pharmacist. 33(4) (pp 53-61), 2008. Date of Publication: 18 Apr 2008.

[Article]

AN: 352066484

Status: Embase

Institution: (Sheth) University of Maryland, School of Pharmacy, Baltimore, MD, United States

Publisher: Jobson Publishing Corporation (100 Avenue of the Americas, New York NY 10013-1678, United States)

Year of Publication: 2008

Link to the Ovid Full Text or citation:
Click here for full text options

70.

Osteoarthritis.

Anonymous

Embase
Pharmacy Times. 74(9) (pp 14-15), 2008. Date of Publication: September 2008.

[Article]

AN: 352582506

Status: Embase

Publisher: Intellisphere LLC (6666 PlainsBoro Road BLDG 300, PlainsBoro,New Jersey 08536, United States)

Year of Publication: 2008

Link to the Ovid Full Text or citation:
Click here for full text options

71.

Topical rubefacients for acute and chronic pain in adults.

Matthews P., Derry S., Moore R.A., McQuay H.J., Moore M.

Embase
Cochrane Database of Systematic Reviews. (4) (no pagination), 2008. Article Number: CD007403. Date of Publication: 2008.

[Review]

AN: 352583878

Status: Embase

Institution: (Derry, Moore, McQuay) Pain Research and Nuffield Department of Anaesthetics, University of Oxford, Oxford, United Kingdom (Matthews) St. Hugh's College, University of Oxford, Oxford, United Kingdom
(Moore) Pain Research and Nuffield Department of Anaesthetics, University of Oxford, John Radcliffe Hospital, Oxford, Oxfordshire, OX3 9DU, United Kingdom

Publisher: John Wiley and Sons Ltd (Southern Gate, Chichester, West Sussex PO19 8SQ, United Kingdom)

Year of Publication: 2008

Link to the Ovid Full Text or citation:
Click here for full text options

72.

Aspirin inhibits the formation of pentosidine, a cross-linking advanced glycation end product, in collagen.

Urios P., Grigorova-Borsos A.-M., Sternberg M.

Embase
Diabetes Research and Clinical Practice. 77(2) (pp 337-340), 2007. Date of Publication: August 2007.

[Letter]

AN: 46670425

Aspirin showed an inhibitory effect on the formation of pentosidine, a cross-linking advanced glycation endproduct, in collagen incubated with glucose in vitro. IC50 was evaluated at 10 mmol/l. Aspirin might act by metallic ion chelating (as did EDTA and DTPA) and by oxygen radical scavenging. Since aspirin was reported to inhibit retinopathy in diabetic dogs, it could act partly by inhibiting advanced glycation endproduct accumulation in long-lived proteins like collagens.

PMID: 17383766 [https://www.ncbi.nlm.nih.gov/pubmed/?term=17383766]

Status: Embase

Institution: (Urios) The Research Group on Modified Proteins and Vascular Endothelium Physiopathology, Laboratory of Pharmacology, Faculty of Pharmacy, France (Urios) Department of Biochemistry, Faculty of Medicine, University of Paris 5, France
(Urios) Laboratory of Biochemistry B, Hopital Bichat, Paris, France
(Grigorova-Borsos) The Research Group on Modified Proteins and Vascular Endothelium Physiopathology, Laboratory of Pharmacology, Faculty of Pharmacy, France
(Grigorova-Borsos) Department of Biochemistry, Faculty of Medicine, University of Paris 5, France
(Sternberg) The Research Group on Modified Proteins and Vascular Endothelium Physiopathology, Laboratory of Pharmacology, Faculty of Pharmacy, France
(Sternberg) Department of Biochemistry, Faculty of Medicine, University of Paris 5, France
(Sternberg) Laboratory of Biochemistry, Hopital St Vincent-de-Paul, 82 av Denfert-Rochereau, 75014 Paris, France

Publisher: Elsevier Ireland Ltd (P.O. Box 85, Limerick, Ireland)

Year of Publication: 2007

Link to the Ovid Full Text or citation:
Click here for full text options

73.

Use of Over-the-Counter Medications and Natural Products in Patients With Moderate and Severe Chronic Renal Insufficiency.

Laliberte M.-C., Normandeau M., Lord A., Lamarre D., Cantin I., Berbiche D., Corneille L., Prud'homme L., Lalonde L.

Embase
American Journal of Kidney Diseases. 49(2) (pp 245-256), 2007. Date of Publication: February 2007.

[Article]

AN: 46172436

Background: Use of over-the-counter medications and natural products may be associated with drug-related problems among patients with chronic renal insufficiency. The aim of this study is to describe the use of nonprescription medications in patients attending a predialysis clinic and identify drug-related problems associated with the use of these products.
Method(s): In a 6-month cluster randomized controlled trial, patients with moderate (n = 46) and severe (n = 41) chronic renal insufficiency were interviewed over the telephone at baseline by a community pharmacist to document their use of over-the-counter medications and natural products. The safety of each product was assessed, and drug-related problems were identified independently by 2 pharmacists.
Result(s): Overall, 83% (95% confidence interval [CI], 72 to 94) of patients with moderate chronic renal insufficiency and 68% (95% CI, 54 to 83) with severe chronic renal insufficiency reported using at least 1 over-the-counter medication. Contraindicated over-the-counter medications were reported by 9% of patients. Natural products were used by 22% (95% CI, 10 to 34) and 29% (95% CI, 15 to 43) of patients with moderate and severe chronic renal

insufficiency, respectively. Similarly, 3% of patients reported using at least 1 contraindicated natural product. Patients had consulted a health professional for 49% of over-the-counter medications and 19% of natural products. Overall, 65 drug-related problems were identified. Conclusion(s): The use of over-the-counter medications and natural products is highly prevalent in patients with chronic renal insufficiency and often is associated with a drug-related problem. These results emphasize the importance for community pharmacists to closely monitor the use of these products in patients with chronic renal insufficiency. © 2007 National Kidney Foundation, Inc.

PMID: 17261427 [https://www.ncbi.nlm.nih.gov/pubmed/?term=17261427]

Status: Embase

Institution: (Laliberte, Normandeau, Lord, Lamarre, Cantin, Berbiche, Corneille, Prud'homme, Lalonde) Faculty of Pharmacy, University of Montreal, Research Team in Primary Care, Quebec, Canada

Publisher: W.B. Saunders (Independence Square West, Philadelphia PA 19106-3399, United States)

Year of Publication: 2007

Link to the Ovid Full Text or citation:
Click here for full text options

74.

Dermatologic considerations regarding the ideal sunscreen.

Draelos Z.D.

Embase
Kosmetische Medizin. 28(1) (pp 8-13), 2007. Date of Publication: 2007.

[Review]

AN: 46736094

Photoprotection is key to preventing premature extrinsic skin aging. The environment is rich in oxidative insults created by the cumulative effects of UV radiation on the skin. While the body is endowed with several self-protective mechanisms, such as carotenoid pigments, melanin, superoxide dismutase, and DNA excision repair, these methods of averting UV insults are quickly overwhelmed. This need for further skin photoprotection has led to the development of topical sunscreens. Sunscreens act by either reflecting or absorbing UV radiation to prevent cutaneous damage. The ideal sunscreen should be efficacious, aesthetically elegant, photostable, and long lasting. These qualities would improve wearing compliance and prevent premature photoaging.

Status: Embase

Institution: (Draelos) Department of Dermatology, Wake Forest University School of Medicine, Winston-Salem, NC, United States (Draelos) 2444 North Main Street, High Point, NC 27262, United States

Publisher: Grosse Verlag GmbH (Brandenburgische Strasse 18, Berlin 10707, Germany)

Year of Publication: 2007

Link to the Ovid Full Text or citation:
Click here for full text options

75.

Salicylate poisoning: An evidence-based consensus guideline for out-of-hospital management.

Chyka P.A., Erdman A.R., Christianson G., Wax P.M., Booze L.L., Manoguerra A.S., Caravati E.M., Nelson L.S., Olson K.R., Cobaugh D.J., Scharman E.J., Woolf A.D., Troutman W.G.

Embase
Clinical Toxicology. 45(2) (pp 95-131), 2007. Date of Publication: February 2007.

[Conference Paper]

AN: 46298476

A review of U.S. poison center data for 2004 showed over 40,000 exposures to salicylate-containing products. A guideline that determines the conditions for emergency department referral and pre-hospital care could potentially optimize patient outcome, avoid unnecessary emergency department visits, reduce health care costs, and reduce life disruption for patients and caregivers. An evidence-based expert consensus process was used to create the guideline. Relevant articles were abstracted by a trained physician researcher. The first draft of the guideline was created by the lead author. The entire panel discussed and refined the guideline before distribution to secondary reviewers for comment. The panel then made changes based on the secondary review comments. The objective of this guideline is to assist poison center personnel in the appropriate out-of-hospital triage and initial out-of-hospital management of patients with a suspected exposure to salicylates by 1) describing the process by which a specialist in poison information should evaluate an exposure to salicylates, 2) identifying the key decision elements in managing cases of salicylate exposure, 3) providing clear and practical recommendations that reflect the current state of knowledge, and 4) identifying needs for research. This guideline is based on an assessment of current scientific and clinical information. The expert consensus panel recognizes that specific patient care decisions may be at variance with this guideline and are the prerogative of the patient and the health professionals providing care, considering all of the circumstances involved. This guideline does not substitute for clinical judgment. Recommendations are in chronological order of likely clinical use. The grade of recommendation is in parentheses: 1) Patients with stated or suspected self-harm or who are the victims of a potentially malicious administration of a salicylate, should be referred to an emergency department immediately. This referral should be guided by local poison center procedures. In general, this should occur regardless of the dose reported (Grade D). 2) The presence of typical symptoms of salicylate toxicity such as hematemesis, tachypnea, hyperpnea, dyspnea, tinnitus, deafness, lethargy, seizures, unexplained lethargy, or confusion warrants referral to an emergency department for evaluation (Grade C). 3) Patients who exhibit typical symptoms of salicylate toxicity or nonspecific symptoms such as unexplained lethargy, confusion, or dyspnea, which could indicate the development of chronic salicylate toxicity, should be referred to an emergency department (Grade C). 4) Patients without evidence of self-harm should have further evaluation, including determination of the dose, time of ingestion, presence of symptoms, history of other medical conditions, and the presence of co-ingestants. The acute ingestion of more than 150 mg/kg or 6.5 g of aspirin equivalent, whichever is less, warrants referral to an emergency department. Ingestion of greater than a lick or taste of oil of wintergreen (98% methyl salicylate) by children under 6 years of age and more than 4 mL of oil of wintergreen by patients 6 years of age and older could cause systemic salicylate toxicity and warrants

referral to an emergency department (Grade C). 5) Do not induce emesis for ingestions of salicylates (Grade D). 6) Consider the out-of-hospital administration of activated charcoal for acute ingestions of a toxic dose if it is immediately available, no contraindications are present, the patient is not vomiting, and local guidelines for its out-of-hospital use are observed. However, do not delay transportation in order to administer activated charcoal (Grade D). 7) Women in the last trimester of pregnancy who ingest below the dose for emergency department referral and do not have other referral conditions should be directed to their primary care physician, obstetrician, or a non-emergent health care facility for evaluation of maternal and fetal risk. Routine referral to an emergency department for immediate care is not required (Grade C). 8) For asymptomatic patients with dermal exposures to methyl salicylate or salicylic acid, the skin should be thoroughly washed with soap and water and the patient can be observed at home for development of symptoms (Grade C). 9) For patients with an ocular exposure of methyl salicylate or salicylic acid, the eye(s) should be irrigated with room-temperature tap water for 15 minutes. If after irrigation the patient is having pain, decreased visual acuity, or persistent irritation, referral for an ophthalmological examination is indicated (Grade D). 10) Poison centers should monitor the onset of symptoms whenever possible by conducting follow-up calls at periodic intervals for approximately 12 hours after ingestion of non-enteric-coated salicylate products, and for approximately 24 hours after the ingestion of enteric-coated aspirin (Grade C).

PMID: 17364628 [https://www.ncbi.nlm.nih.gov/pubmed/?term=17364628]

Status: Embase

Institution: (Chyka, Erdman, Christianson, Wax, Booze, Manoguerra, Caravati, Nelson, Olson, Cobaugh, Scharman, Woolf, Troutman) American Association of Poison Control Centers, Washington, DC, United States

Publisher: Informa Healthcare (69-77 Paul Street, London EC2A 4LQ, United Kingdom)

Year of Publication: 2007

Link to the Ovid Full Text or citation:
Click here for full text options

76.

Phase III trial of an emulsion containing trolamine for the prevention of radiation dermatitis in patients with advanced squamous cell carcinoma of the head and neck: Results of Radiation Therapy Oncology Group trial 99-13.

Elliott E.A., Wright J.R., Swann R.S., Nguyen-Tan F., Takita C., Bucci M.K., Garden A.S., Kim H., Hug E.B., Ryu J., Greenberg M., Saxton J.P., Ang K., Berk L.

Embase
Journal of Clinical Oncology. 24(13) (pp 2092-2097), 2006. Date of Publication: 01 May 2006.

[Article]

AN: 46622120

Purpose: This multicentered phase III trial was designed to compare an emulsion containing trolamine against the usual supportive care within each participating institution for patients with head and neck cancer undergoing radiation therapy.

Patients and Methods: Patients with biopsy-proven squamous cell carcinoma of the oral cavity, oropharynx, hypopharynx, or larynx were randomly assigned to one of the following treatments: prophylactic trolamine emulsion, interventional trolamine emulsion, or declared institutional preference. The primary outcome was the reduction in grade 2 or higher skin toxicity, as per National Cancer Institute Common Toxicity Criteria version 2.0. Secondary outcomes included patient-reported quality of life (QOL).
Result(s): From October 2000 to April 2002, 547 patients from 51 institutions were entered onto the trial. The average age was 59 years. Patients were predominately male (79%) and most continued to use tobacco products (52%). The rates of grade 2 or higher radiation dermatitis were 79%, 77%, and 79% in the prophylactic, interventional, and institutional preference arms of the study, respectively. No significant differences in QOL were found.
Conclusion(s): The results of this trial demonstrate no advantage for the use of trolamine in reducing the incidence of grade 2 or higher radiation dermatitis or improving patient-reported QOL. The use of 15 different local standards of care highlights the need to continue research that will result in evidence-based recommendations to reduce the burden of radiation dermatitis.

PMID: 16648511 [https://www.ncbi.nlm.nih.gov/pubmed/?term=16648511]

Status: Embase

Institution: (Elliott) Juravinski Cancer Centre, 699 Concession St, Hamilton, Ont. L8V5C2, Canada

Publisher: American Society of Clinical Oncology (330 John Carlyle Street, Suite 300, Alexandria VA 22314, United States)

Year of Publication: 2006

Link to the Ovid Full Text or citation:
Click here for full text options

77.

Cosmetic dermatology: A review of skin care.

Draelos Z.D.

Embase
Giornale Italiano di Dermatologia e Venereologia. 140(5) (pp 515-529), 2005. Date of Publication: 2005.

[Review]

AN: 43942766

Dermatologic treatment involves 2 phases: therapeutic and maintenance. The therapeutic phase of dermatologic treatment includes the diagnosis of the condition and the development of a plan to alleviate the signs and symptoms of disease. The maintenance phase of dermatologic treatment involves the recommendation of a skin care routine that prevents the recurrence of the disease state, since failure to identify and eliminate the causative factors will result in disease recurrence. This review article deals with the maintenance phase of dermatologic treatment by discussing the use of cleansers, moisturizers, sunscreens, and facial cosmetics to maintain the integrity of the skin barrier and the ultimate health of the skin.

Status: Embase

Institution: (Draelos) Department of Dermatology, Wake Forest University School of Medicine, Winston-Salem, NC, United States (Draelos) Dermatology Consulting Services, High Point, NC, United States
(Draelos) 2444 North Main Street, High Point, NC 27262, United States

Publisher: Edizioni Minerva Medica (E-mail: subscriptions.dept@minervamedica.it)

Year of Publication: 2005

78.

Deep percutaneous penetration into muscles and joints.

Lee C.M., Maibach H.I.

Embase
Journal of Pharmaceutical Sciences. 95(7) (pp 1405-1413), 2006. Date of Publication: July 2006.

[Review]

AN: 44049110

The transdermal absorption of drugs and its subsequent deep tissue delivery is a complex process, with many factors influencing the penetration mechanisms. Nonsteroidal antiinflammatory drugs (NSAIDs) are widely used in the treatment of joint and muscle diseases. However, the dangers associated with oral medications highlight the need for alternative methods of targeting and retaining drugs; one such means is through topical delivery. The drug's lipophilicity, permeability, and fraction unbound found in the viable skin are some physiochemical factors influencing the delivery mechanism after transdermal absorption. These and other variables play a role in determining whether the drug reaches the deep tissues via direct penetration or from systemic redistribution. Pharmacokinetic

models have been developed to help elucidate the penetration routes and efficacy for various drugs. While there are still uncertainties regarding the deep tissue penetration kinetics, improvements to current research methodologies may bring about a greater understanding of percutaneous absorption into the deep muscle and joints. © 2006 Wiley-Liss, Inc.

PMID: 16729269 [https://www.ncbi.nlm.nih.gov/pubmed/?term=16729269]

Status: Embase

Institution: (Lee, Maibach) Department of Dermatology, University of California, 90 Medical Center Way, San Francisco, CA 94143-0989, United States

Publisher: John Wiley and Sons Inc. (P.O.Box 18667, Newark NJ 07191-8667, United States)

Year of Publication: 2006

79.

Skin manifestations of running.

Mailler-Savage E.A., Adams B.B.

Embase
Journal of the American Academy of Dermatology. 55(2) (pp 290-301), 2006. Date of Publication: August 2006.

[Review]

AN: 44038014

As the United States comes increasingly closer to being the heaviest nation on earth, many people are turning to exercise, especially running, to lose weight. Most runners, whether novice or professional, will have a skin disorder that may prompt them to seek medical attention. Although case reports and sports reviews have discussed, in a cursory fashion, the

nature of these skin lesions, to our knowledge there has never been an extensive review of the literature that specifically addresses the skin diseases of runners. In this article, we present the epidemiology, origin, clinical characteristics, treatment, and prevention of skin diseases inherent to runners. © 2006 American Academy of Dermatology, Inc.

PMID: 16844514 [https://www.ncbi.nlm.nih.gov/pubmed/?term=16844514]

Status: Embase

Institution: (Mailler-Savage, Adams) Department of Dermatology, University of Cincinnati, United States (Adams) Veterans Administration Medical Center, United States

Publisher: Mosby Inc. (11830 Westline Industrial Drive, St. Louis MO 63146, United States)

Year of Publication: 2006

80.

Novel emerging sunscreen technologies.

Tuchinda C., Lim H.W., Osterwalder U., Rougier A.

Embase
Dermatologic Clinics. 24(1) (pp 105-117), 2006. Date of Publication: January 2006.

[Review]

AN: 41727639

To improve the efficacy and safety of sunscreen products, UV filters and efficient photostable UVA and broadband UVB/UVA filters have been developed. Other new technologies, including a nonabsorbing material to boost SPF, coating/modifications of inorganic sunscreen, stabilizing avobenzone by photostabilizers, encapsulation of UV absorbers, and microfine organic particles also may improve efficacy and safety of sun protective products.

In the near future, new sunscreen products with even better in efficacy and safety should become available all over the world.

PMID: 16311173 [https://www.ncbi.nlm.nih.gov/pubmed/?term=16311173]

Status: Embase

Institution: (Tuchinda, Lim) Department of Dermatology, Henry Ford Hospital, Detroit, MI, United States (Osterwalder) Ciba Specialty Chemicals, Basel, Switzerland
(Rougier) La Roche-Posay Pharmaceutical Laboratories, Asnieres, France
(Lim) Department of Dermatology, Henry Ford Hospital, 3031 West Grand Boulevard, Detroit, MI 48303, United States

Publisher: W.B. Saunders (Independence Square West, Philadelphia PA 19106-3399, United States)

Year of Publication: 2006

Link to the Ovid Full Text or citation:
Click here for full text options

81.

Marigold (Calendula officinalis L.): An evidence-based systematic review by the natural standard research collaboration.

Basch E., Bent S., Foppa I., Haskmi S., Kroll D., Mele M., Szapary P., Ulbricht C., Vora M., Yong S.

Embase
Journal of Herbal Pharmacotherapy. 6(3-4) (pp 135-159), 2006. Date of Publication: 2006.

[Review]

AN: 46403777

An evidence-based systematic review including written and statistical analysis of scientific literature, expert opinion, folkloric precedent, history, pharmacology, kinetics/dynamics, interactions, adverse effects, toxicology and dosing.

PMID: 17317655 [https://www.ncbi.nlm.nih.gov/pubmed/?term=17317655]

Status: Embase

Institution: (Basch) Memorial Sloan-Kettering Cancer Center, University of California, San Francisco, CA, United States (Bent) University of California, San Francisco, CA, United States
(Foppa) University of South Carolina, Columbia, SC, United States
(Haskmi) Harvard School of Public Health, Boston, MA, United States
(Kroll) Duke University, Durham, NC, United States
(Mele, Vora) Northeastern University, Boston, MA, United States
(Szapary) University of Pennsylvania, Pittsburgh, PA, United States
(Ulbricht) Massachusetts General Hospital, Boston, MA, United States
(Yong) Massachusetts College of Pharmacy and Health Sciences, Boston, MA, United States

Publisher: Informa Healthcare (69-77 Paul Street, London EC2A 4LQ, United Kingdom)

Year of Publication: 2006

82.

Photoprotection insights.

Draelos Z.D.

Embase
Cosmetic Dermatology. 19(9) (pp 563-564), 2006. Date of Publication: September 2006.

[Short Survey]

AN: 44465327

Sunscreens remain an important part of dermatology, with new developments creating longer lasting, more aesthetic photoprotection. Current sunscreen research is aimed at creating better polymers to increase the length of time the sunscreen film remains in place on the skin, despite the presence of sebum and perspiration. Polymers also can suspend particulates, such as zinc oxide and titanium dioxide, allowing the film to be invisible on the skin. Hopefully, the incorporation of new approved actives in the sunscreen monograph will further broaden skin photoprotection.

Status: Embase

Institution: (Draelos) Department of Dermatology, Wake Forest University, School of Medicine, Winston-Salem, NC, United States (Draelos) Dermatology Consisting Services, High Point, NC, United States

Publisher: Quadrant Healthcom Inc. (7 Century Drive, Suite 302, Parsippany NJ 07054-4609, United States)

Year of Publication: 2006

Link to the Ovid Full Text or citation:
Click here for full text options

83.

Intravenous immunoglobulin for treatment of toxic epidermal necrolysis.

Nasser M., Bitterman-Deutsch O., Nassar F.

Embase
American Journal of the Medical Sciences. 329(2) (pp 95-98), 2005. Date of Publication: February 2005.

[Article]

AN: 40250600

We report three female patients suffering from toxic epidermal necrolysis, with 30% to 70% epidermal detachment. Alleged causative agents were dipyrone, dibenzazepine, and allopurinol. All patients were treated by intravenous immunoglobulins (IVIG) and survived without further complications, although poor prognostic factors such as concomitant diabetes, large areas of epidermal detachment, and pancytopenia were present. We report these cases with emphasis on the concept that prompt diagnosis, withdrawal of causative drugs, and immediate treatment are imperative for the favorable outcome of the disease. Our patients can be added to the list of those patients who were successfully treated by IVIG, as indicated in this review of the literature.

PMID: 15711426 [https://www.ncbi.nlm.nih.gov/pubmed/?term=15711426]

Status: Embase

Institution: (Nasser, Nassar) Department of Internal Medicine E, Western Galilee Hospital, Nahariya, Israel (Bitterman-Deutsch) Dermatology Clinic, Western Galilee Hospital, Nahariya, Israel

Publisher: Lippincott Williams and Wilkins (530 Walnut Street,P O Box 327, Philadelphia PA 19106-3621, United States)

Year of Publication: 2005

Link to the Ovid Full Text or citation:
Click here for full text options

84.

Photoprotection.

Kullavanijaya P., Lim H.W.

Embase
Journal of the American Academy of Dermatology. 52(6) (pp 937-958), 2005. Date of Publication: June 2005.

[Review]

AN: 40732532

Many agents affect the transmission of ultraviolet light to human skin. These include naturally occurring photoprotective agents (ozone, pollutants, clouds, and fog), naturally occurring biologic agents (epidermal chromophores), physical photoprotective agents (clothing, hats, make-ups, sunglasses, and window glass), and ultraviolet light filters (sunscreen ingredients and sunless tanning agents). In addition, there are agents that can modulate the effects of ultraviolet light on the skin (antioxidants and others). All of the above are reviewed in this article. At the conclusion of this learning activity, participants should be able to provide an overview of all aspects of photoprotection. © 2005 by the American Academy of Dermatology, Inc.

PMID: 15928611 [https://www.ncbi.nlm.nih.gov/pubmed/?term=15928611]

Status: Embase

Institution: (Kullavanijaya, Lim) Department of Dermatology, Henry Ford Hospital, Detroit, MI, United States (Lim) Department of Dermatology, Henry Ford Hospital, 2799 W Grand Blvd, Detroit, MI 48202, United States

Publisher: Mosby Inc. (11830 Westline Industrial Drive, St. Louis MO 63146, United States)

Year of Publication: 2005

Link to the Ovid Full Text or citation:
Click here for full text options

85.

Calendula ointment and radiation dermatitis during breast cancer treatment.

Hudson T.

Embase

Alternative and Complementary Therapies. 11(1) (pp 39-40), 2005. Date of Publication: February 2005.

[Note]

AN: 40269979

Status: Embase

Institution: (Hudson) Department of Gynecology, Natl. Coll. of Naturopathic Medicine, Portland, OR, United States (Hudson) A Woman's Time, Portland, OR, United States

Publisher: Mary Ann Liebert Inc. (140 Huguenot Street, New Rochelle NY 10801-5215, United States)

Year of Publication: 2005

Link to the Ovid Full Text or citation:
Click here for full text options

86.

Advances in rheumatology: Coxibs and beyond.

Kuritzky L., Weaver A.

Embase
Journal of Pain and Symptom Management. 25(2 SUPPL.) (pp 6-20), 2003. Date of Publication: 01 Feb 2003.

[Review]

AN: 36258338

Arthritis is a growing health concern in the US with approximately 70 million Americans currently affected. This figure will inevitably rise as the population ages. The pain and decreased mobility associated with arthritis have a significant impact on quality of life and

because patients with arthritis are less active than the general population, they are at risk of additional conditions such as obesity, heart disease, diabetes, and hypertension. There are currently no disease modifying osteoarthritis (OA) drugs available; therefore anti-inflammatory, and/or analgesic medications such as acetaminophen and NSAIDs and simple analgesics form the mainstay of treatment. Coxibs may be preferred to traditional NSAIDs because of their improved gastrointestinal (GI) safety and tolerability profile. The use of topical agents may also be beneficial in some patients. In rheumatoid arthritis (RA) where disease modifying drugs (DMARDs) are available, anti-inflammatory agents such as NSAIDs and coxibs are used as adjuncts to disease modifying therapy. However, patients with RA are at increased risk of NSAID-related GI injury, particularly if they are also on corticosteroid medication. Pharmacological treatment of both RA and OA should be combined with appropriate nonpharmacological modalities such as patient education, exercise programs, and joint motion and strengthening exercises. Such activities may delay joint degradation and help maintain physical function.

PMID: 12604153 [https://www.ncbi.nlm.nih.gov/pubmed/?term=12604153]

Status: Embase

Institution: (Kuritzky) Dept. of Comm. Hlth./Family Medicine, University of Florida, Gainesville, FL, United States (Weaver) Univ. of Nebraska Medical Center, Omaha, NE, United States
(Kuritzky) Dept. of Comm. Hlth./Family Medicine, University of Florida, Box 103588, Gainesville, FL 32608, United States

Publisher: Elsevier Inc.

Year of Publication: 2003

Link to the Ovid Full Text or citation:
Click here for full text options

87.

Over-the-counter topical antipruritic agents are commonly recommended by office-based physicians: An analysis of US practice patterns.

Duque M.I., Vogel C.A., Fleischer Jr. A.B., Yosipovitch G.

Embase
Journal of Dermatological Treatment. 15(3) (pp 185-188), 2004. Date of Publication: June 2004.

[Article]

AN: 39214581

BACKGROUND: Pruritus is one of the most common complaints among patients who visit physicians. Over-the-counter topical antipruritic medications are widely recommended by physicians and are self-administered by patients for the treatment of pruritus. However, there are few scientific controlled studies evaluating the effect of these drugs on pruritus.
OBJECTIVE(S): To assess the role of physician-recommended over-the-counter medications for the treatment of pruritus.
METHOD(S): Records were analyzed for office-based physician visits in which over-the-counter antipruritic topical medications were recommended in the National Ambulatory Medical Care Survey between the years 1995 and 2000.
RESULT(S): The largest proportion of over-the-counter antipruritic agent recommendations were during visits to dermatologists, accounting for 41% of all such recommendations. Other physicians that recommended such agents included family physicians and pediatricians, accounting respectively for 26% and 21% of the recommendations. The most commonly recommended over-the-counter medications included hydrocortisone preparations (72%) and diphenhydramine (15%). Over-the-counter medications were more frequently recommended in the pediatric age group.
CONCLUSION(S): This study demonstrates that over-the-counter medications are frequently recommended for the treatment of pruritus.

PMID: 15204153 [https://www.ncbi.nlm.nih.gov/pubmed/?term=15204153]

Status: Embase

Institution: (Duque, Vogel, Fleischer Jr., Yosipovitch) Department of Dermatology, Wake Forest Univ. School of Medicine, Winston-Salem, NC, United States (Yosipovitch) Department of Dermatology, Wake Forest Univ. School of Medicine, Medical Center Boulevard, Winston Salem, NC 27157, United States

Publisher: Informa Healthcare (69-77 Paul Street, London EC2A 4LQ, United Kingdom)

Year of Publication: 2004

88.

Photoprotection by sunscreens with topical antioxidants and systemic antioxidants to reduce sun exposure.

Edlich R.F., Winters K.L., Lim H.W., Cox M.J., Becker D.G., Horowitz J.H., Nichter L.S., Britt L.D., Long W.B.

Embase
Journal of Long-Term Effects of Medical Implants. 14(4) (pp 317-340), 2004. Date of Publication: 2004.

[Review]

AN: 39128603

Skin cancer is the most common cancer diagnosed in the United States, and its incidence continues to rise. Epidemiological studies have documented that excessive sun exposure increases the risk of developing nonmelanoma skin cancer. Consequently, it is mandatory that the skin be protected from the damage that occurs from ultraviolet (UV) exposure. It is the purpose of this report to review the scientific basis for photoprotection by sunscreens, topical antioxidants, and systemic antioxidants to minimize the harmful effect of sun exposure. The US Food and Drug Administration regulates sunscreen products as over-the-counter drugs. Sunscreens are chemical or organic UV absorbers and nonchemical or inorganic UV absorbers. Other important sunscreen considerations include the sunscreen vehicle, sunscreen photostability, sunscreen preservatives, and sunscreen photoallergy and phototoxicity. Topical and systemic antioxidants have now been shown to supplement the photoprotective effects of sunscreen. The Skin Cancer Foundation, the only national and

international nonprofit organization concerned exclusively with cancer of the skin, is playing a leadership role in eliminating skin cancer in our world.

PMID: 15447629 [https://www.ncbi.nlm.nih.gov/pubmed/?term=15447629]

Status: Embase

Institution: (Edlich, Winters) Plastic Surgical Research Program, University of Virginia Health System, Charlottesville, VA, United States (Lim) Department of Dermatology, Henry Ford Health System, Detroit, MI, United States
(Lim) Skin Cancer Foundation, Australia
(Cox) Eye Phys. of Southern New Jersey, Somerdale, NJ, United States
(Becker) Univ. of Pennsylvania Sch. of Med., Philadelphia, PA, United States
(Horowitz, Nichter) Pacific Center for Plastic Surgery, Huntington Beach, CA, United States
(Britt) Department of General Surgery, Eastern Virginia Medical School, Norfolk, VA, United States
(Long) Trauma Services, Legacy Emanuel Hospital, Portland, OR, United States
(Edlich) 16155 NW Jenne Lake Ct., Beaverton, OR 97006, United States

Publisher: Begell House Inc. (50 Cross Highway, Redding CT 06886, United States)

Year of Publication: 2004

Link to the Ovid Full Text or citation:
Click here for full text options

89.

Sorting through sunscreen choices.

Miller P.

Embase
Canadian Pharmaceutical Journal. 137(5) (pp 39-43), 2004. Date of Publication: June 2004.

[Review]

AN: 39093729

Sun protection strategies include seeking shade, avoiding peak sunlight hours and wearing a wide-brimmed hat, tightly woven clothing, and sunglasses. Sunscreens are not intended to prolong sun exposure. There is no safe tan - a suntan is the skin's response to injury. Sunburn prevention is vital for fair-skinned persons, but skin cancer prevention is important for all skin types. The selection of a sunscreen should block both UVB and UVA wavelengths and have an SPF of at least 15. Ideal broad spectrum sunscreens will typically contain multiple agents and should be applied in the recommended manner. The widespread adoption of regular broad spectrum sunscreen use can decrease sunburns, photoaging, and the development of actinic keratosis. Most experts propose that squamous cell, basal cell, and malignant melanoma risk will be reduced in the future with safe sun exposure behaviours.

Status: Embase

Institution: (Miller) Faculty of Pharmaceutical Sciences, Department of Family Practice, University of British Columbia, Vancouver, BC, Canada

Publisher: Canadian Pharmacists Association (1785 Alta Vista Drive, Ottawa ON K1G 3Y6, Canada)

Year of Publication: 2004

Link to the Ovid Full Text or citation:
Click here for full text options

90.

Safety and acceptability of penile application of 2 candidate topical microbicides: BufferGel and PRO 2000 Gel. 3 Randomized trials in healthy low-risk men and HIV-positive men.

Tabet S.R., Callahan M.M., Mauck C.K., Gai F., Coletti A.S., Profy A.T., Moench T.R., Soto-Torres L.E., Poindexter III A.N., Frezieres R.G., Walsh T.L., Kelly C.W., Richardson B.A., Van Damme L., Celum C.L.

Embase

Journal of Acquired Immune Deficiency Syndromes. 33(4) (pp 476-483), 2003. Date of Publication: 01 Aug 2003.

[Article]

AN: 36886076

Objectives: To assess safety and acceptability of penile application of BufferGel (ReProtect, Baltimore, MD) and PRO 2000 Gel (Indevus Pharmaceuticals, Lexington, MA)compared with placebo among low-risk sexually abstinent men and HIV-positive sexually abstinent men.
Design(s): Seventy-two healthy low-risk men (36 uncircumcised) and 25 HIV-positive men (12 uncircumcised) were enrolled in 3 double-blind, single-center studies as follows: 36 low-risk men in a study of BufferGel and K-Y Jelly (McNeil-PPC, Skillman, NJ) placebo; 36 low-risk men in a study of PRO 2000 Gel and vehicle placebo; and 25 HIV-positive men in a crossover study of BufferGel, PRO 2000 Gel, and K-Y Jelly placebo.
Method(s): Participants applied product to the penis on 7 consecutive nights, kept study diaries, and were then interviewed and examined. Urine was tested for inflammation by leukocyte esterase.
Result(s): No serious adverse events (AEs) or urethral inflammation was detected. During use of BufferGel, 3 low-risk men (13%) reported 6 AEs and 2 HIV-positive men (8%) reported 3 AEs. During use of PRO 2000 Gel, 4 low-risk men (17%) reported 6 AEs and 1 HIV-positive participant (4%) had 1 AE. AE rates during use of BufferGel and PRO 2000 Gel use were not significantly different from rates observed during placebo. One low-risk man (4%) would object to his partners using BufferGel and 3 (13%) to PRO 2000 Gel. Two HIV-positive men (8%) reported they would object to partners using either BufferGel or PRO 2000 Gel.
Conclusion(s): Daily application of BufferGel and PRO 2000 Gel directly to the penis consecutively for 7 days was generally safe and well tolerated among healthy low-risk men and HIV-positive men. These microbicides have acceptable safety profiles to proceed with planned phase 3 vaginal microbicide trials.

PMID: 12869836 [https://www.ncbi.nlm.nih.gov/pubmed/?term=12869836]

Status: Embase

Institution: (Tabet, Celum) Department of Medicine, University of Washington, Seattle, WA, United States (Callahan, Mauck, Van Damme) Contraceptive Res./Devmt. Program, Arlington, VA, United States
(Gai, Kelly) Fred Hutchinson Cancer Res. Center, Seattle, WA, United States

(Coletti) Family Health International, Research Triangle Park, NC, United States
(Profy) Indevus Pharmaceuticals, Inc., Lexington, MA, United States
(Moench) ReProtect, Inc., Baltimore, MD, United States
(Soto-Torres) Natl. Inst. of Allerg./Infect. Dis., National Institutes of Health, Dept. of Health and Human Services, Bethesda, MD, United States
(Poindexter III) Department of Obstetrics, Baylor College of Medicine, Houston, TX, United States
(Frezieres, Walsh) California Fam. Health Council, Inc., Los Angeles, CA, United States
(Richardson) Department of Biostatistics, University of Washington, Seattle, WA, United States
(Tabet) University of Washington, HIV Prevention Trials, Unit 901, Boren Avenue, Seattle, WA 98104, United States

Publisher: Lippincott Williams and Wilkins (530 Walnut Street,P O Box 327, Philadelphia PA 19106-3621, United States)

Year of Publication: 2003

Link to the Ovid Full Text or citation:
Click here for full text options

91.

Safety Assessment of Salicylic Acid, Butyloctyl Salicylate, Calcium Salicylate, C12-15 Alkyl Salicylate, Capryloyl Salicylic Acid, Hexyldodecyl Salicylate, Isocetyl Salicylate, Isodecyl Salicylate, Magnesium Salicylate, (see abstract).

Andersen F.A.

Embase
International Journal of Toxicology. 22(SUPPL. 3) (pp 1-108), 2003. Date of Publication: 2003.

[Review]

AN: 38111143

Salicylic Acid is an aromatic acid used in cosmetic formulations as a denaturant, hair-conditioning agent, and skin-conditioning agent-miscellaneous in a wide range of cosmetic products at concentrations ranging from 0.0008% to 3%. The Calcium, Magnesium, and MEA salts are preservatives, and Potassium Salicylate is a cosmetic biocide and preservative, not currently in use. Sodium Salicylate is used as a denaturant and preservative (0.09% to 2%). The TEA salt of Salicylic Acid is used as an ultraviolet (UV) light absorber (0.0001% to 0.75%). Several Salicylic Acid esters are used as skin conditioning agents-miscellaneous (Capryloyl, 0.1% to 1%; C12-15 Alkyl, no current use; Isocetyl, 3% to 5%; Isodecyl, no current use; and Tridecyl, no current use). Butyloctyl Salicylate (0.5% to 5%) and Hexyldodecyl Salicylate (no current use) are hair-conditioning agents and skin-conditioning agents-miscellaneous. Ethylhexyl Salicylate (formerly known as Octyl Salicylate) is used as a fragrance ingredient, sunscreen agent, and UV light absorber (0.001% to 8%), and Methyl Salicylate is used as a denaturant and flavoring agent (0.0001% to 0.6%). Myristyl Salicylate has no reported function. Isodecyl Salicylate is used in three formulations, but no concentration of use information was reported. Salicylates are absorbed percutaneously. Around 10% of applied salicylates can remain in the skin. Salicylic Acid is reported to enhance percutaneous penetration of some agents (e.g., vitamin A), but not others (e.g., hydrocortisone). Little acute toxicity (LD50 in rats; >2 g/kg) via a dermal exposure route is seen for Salicylic Acid, Methyl Salicylate, Tridecyl Salicylate, and Butyloctyl Salicylate. Short-term oral, inhalation, and parenteral exposures to salicylates sufficient to produce high blood concentrations are associated primarily with liver and kidney damage. Subchronic dermal exposures to undiluted Methyl Salicylate were associated with kidney damage. Chronic oral exposure to Methyl Salicylate produced bone lesions as a function of the level of exposure in 2-year rat studies; liver damage was seen in dogs exposed to 0.15 g/kg/day in one study; kidney and liver weight increases in another study at the same exposure; but no liver or kidney abnormalities in a study at 0.167 g/kg/day. Applications of Isodecyl, Tridecyl, and Butyloctyl Salicylate were not irritating to rabbit skin, whereas undiluted Ethylhexyl Salicylate produced minimal to mild irritation. Methyl Salicylate at a 1% concentration with a 70% ethanol vehicle were irritating, whereas a 6%% concentration in polyethylene glycol produced little or no irritation. Isodecyl Salicylate, Methyl Salicylate, Ethylhexyl (Octyl) Salicylate, Tridecyl Salicylate, and Butyloctyl Salicylate were not ocular irritants. Although Salicylic Acid at a concentration of 20% in acetone was positive in the local lymph node assay, a concentration of 20% in acetone/olive oil was not. Methyl Salicylate was negative at concentrations up to 25% in this assay, independent of vehicle. Maximization tests of Methyl Salicylate, Ethylhexyl Salicylate, and Butyloctyl Salicylate produced no sensitization in guinea pigs. Neither Salicylic Acid nor Tridecyl Salicylate were photosensitizers. Salicylic Acid, produced when aspirin is rapidly hydrolyzed after absorption from the gut, was reported to be the causative agent in aspirin teratogenesis in animals. Dermal exposures to Methyl Salicylate, oral exposures to Salicylic

Acid, Sodium Salicylate, and Methyl Salicylate, and parenteral exposures to Salicylic Acid, Sodium Salicylate, and Methyl Salicylate are all associated with reproductive and developmental toxicity as a function of blood levels reached as a result of exposure. An exposure assessment of a representative cosmetic product used on a daily basis estimated that the exposure from the cosmetic product would be only 20% of the level seen with ingestion of a "baby" aspirin (81 mg) on a daily basis. Studies of the genotoxic potential of Salicylic Acid, Sodium Salicylate, Isodecyl Salicylate, Methyl Salicylate, Ethylhexyl (Octyl) Salicylate, Tridecyl Salicylate, and Butyloctyl Salicylate were generally negative. Methyl Salicylate, in a mouse skin-painting study, did not induce neoplasms. Likewise, Methyl Salicylate was negative in a mouse pulmonary tumor system. In clinical tests, Salicylic Acid (2%) produced minimal cumulative irritation and slight or no irritation(1.5%); TEA-Salicylate (8%) produced no irritation; Methyl Salicylate (>12%) produced pain and erythema, a 1% aerosol produced erythema, but an 8% solution was not irritating; Ethylhexyl Salicylate (4%) and undiluted Tridecyl Salicylate produced no irritation. In atopic patients, Methyl Salicylate caused irritation as a function of concentration (no irritation at concentrations of 15% or less). In normal skin, Salicylic Acid, Methyl Salicylate, and Ethylhexyl (Octyl) Salicylate are not sensitizers. Salicylic Acid is not a photosensitizer, nor is it phototoxic. Salicylic Acid and Ethylhexyl Salicylate are low-level photoprotective agents. Salicylic Acid is well-documented to have keratolytic action on normal human skin. Because of the possible use of these ingredients as exfoliating agents, a concern exists that repeated use may effectively increase exposure of the dermis and epidermis to UV radiation. It was concluded that the prudent course of action would be to advise the cosmetics industry that there is a risk of increased UV radiation damage with the use of any exfoliant, including Salicylic Acid and the listed salicylates, and that steps need to be taken to formulate cosmetic products with these ingredients as exfoliating agents so as not to increase sun sensitivity, or when increased sun sensitivity would be expected, to include directions for the daily use of sun protection. The available data were not sufficient to establish a limit on concentration of these ingredients, or to identify the minimum pH of formulations containing these ingredients, such that no skin irritation would occur, but it was recognized that it is possible to formulate cosmetic products in a way such that significant irritation would not be likely, and it was concluded that the cosmetics industry should formulate products containing these ingredients so as to be nonirritating.

PMID: 14617432 [https://www.ncbi.nlm.nih.gov/pubmed/?term=14617432]

Status: Embase

Institution: (Andersen) Cosmetic Ingredient Review, 1101 17th Street, NW, Washington, DC 20036, United States

Publisher: SAGE Publications Inc. (2455 Teller Road, Thousand Oaks CA 91320, United States)

Year of Publication: 2003

Link to the Ovid Full Text or citation:
Click here for full text options

92.

Topical ketamine treatment of postherpetic neuralgia.

Quan D., Wellish M., Gilden D.H.

Embase
Neurology. 60(8) (pp 1391-1392), 2003. Date of Publication: 22 Apr 2003.

[Article]

AN: 36461006

PMID: 12707455 [https://www.ncbi.nlm.nih.gov/pubmed/?term=12707455]

Status: Embase

Institution: (Quan, Wellish, Gilden) Department of Neurology, University of Colorado, Health Sciences Center, 4200 East 9th Avenue, Denver, CO 80262, United States (Gilden) Department of Microbiology, University of Colorado, Health Sciences Center, Denver, CO, United States

Publisher: Lippincott Williams and Wilkins (530 Walnut Street,P O Box 327, Philadelphia PA 19106-3621, United States)

Year of Publication: 2003

93.

An in vitro systematic spectroscopic examination of the photostabilities of a random set of commercial sunscreen lotions and their chemical UVB/UVA active agents.

Serpone N., Salinaro A., Emeline A.V., Horikoshi S., Hidaka H., Zhao J.

Embase
Photochemical and Photobiological Sciences. 1(12) (pp 970-981), 2002. Date of Publication: 01 Dec 2002.

[Review]

AN: 37069826

The photostabilities of a random set of commercially available sunscreen lotions and their active ingredients are examined spectroscopically subsequent to simulated sunlight UV exposure. Loss of filtering efficacy can occur because of possible photochemical modifications of the sunscreen active agents. Changes in absorption of UVA/UVB sunlight by agents in sunscreen lotions also leads to a reduction of the expected photoprotection of human skin and DNA against the harmful UV radiation. The active ingredients were investigated in aqueous media and in organic solvents of various polarities (methanol, acetonitrile, and n-hexane) under aerobic and anaerobic conditions. The UV absorption features are affected by the nature of the solvents with properties closely related to oil-in-water (o/w) or water-in-oil (w/o) emulsions actually used in sunscreen formulations, and by the presence of molecular oxygen. The photostabilities of two combined chemical ingredients (oxybenzone and octyl methoxycinnamate) and the combination oxybenzone/titanium dioxide were also explored. In the latter case, oxybenzone undergoes significant photodegradation in the presence of the physical filter TiO2.

Status: Embase

Institution: (Serpone, Salinaro, Emeline) Department of Chemistry/Biochemistry, Concordia University, 1455 de Maisonneuve Blvd. West, Montreal, Que. H3G 1MB, Canada (Horikoshi, Hidaka) Frontier Research Center, Global Environment Protection, Meisei University, 2-1-1 Hodokubo, Hino, Tokyo 191-8506, Japan
(Zhao) The Laboratory of Photochemistry, Center for Molecular Sciences, Institute of Chemistry, Beijing 100 080, China

Publisher: Royal Society of Chemistry

Year of Publication: 2002

94.

Use of ferric chloride to identify salicylate-containing poisons.

Hoffman R.J., Nelson L.S., Hoffman R.S.

Embase
Journal of Toxicology - Clinical Toxicology. 40(5) (pp 547-549), 2002. Date of Publication: 2002.

[Article]

AN: 34971205

Objective: Ferric chloride (FeCl3) is used to qualitatively test the urine of patients with presumed salicylate exposure. FeCl3 testing of an unidentified poison might provide evidence of salicylate exposure in situations where FeCl3 urine testing cannot be used. Such situations include the absence of a urine sample, immediately after ingestion before urine contains a detectable quantity of salicylate, or for patients chronically using salicylates for which FeCl3 testing is unhelpful. This study seeks to determine if FeCl3 can be used to identify salicylate-containing products.
Method(s): We assessed the reactivity of FeCl3 with commercially available salicylate-containing products. We applied 0.1 mL of 10% FeCl3 solution to each of 15 various

salicylate-containing products including: regular and buffered acetylsalicylic acid, bismuth subsalicylate, methylsalicylate, physostigmine salicylate, salicylic acid, trolamine salicylate, and herbal tablets with salicin- containing white willow bark (Salix sp.). These products tested were: regular and enteric-coated pills (n = 4), powder (n = 1), topical creams (n = 5), topical liquids (n = 4), and intravenous solution (n = 1). FeCl3 was applied to crushed tablets and added directly to liquids and creams. Fifteen salicylate-free controls including liquids, pills, and creams similar in appearance to experimental samples were also tested. Three blinded physicians familiar with FeCl3 testing independently observed the addition of FeCl3 to each sample and rated a positive or negative result.
Result(s): All salicylate-containing products were interpreted to be clearly FeCl3 positive and all control samples were interpreted to be clearly FeCl3 negative.
Conclusion(s): Salicylate-containing products may be identified using FeCl3. When using FeCl3 testing as described herein, only a positive test result should be applied; any negative result should be considered inconclusive.

PMID: 12215048 [https://www.ncbi.nlm.nih.gov/pubmed/?term=12215048]

Status: Embase

Institution: (Hoffman, Nelson, Hoffman) New York City Poison Control Center, 455 First Avenue, New York, NY 10016, United States

Publisher: Taylor and Francis Inc. (325 Chestnut St, Suite 800, Philadelphia PA 19106, United States)

Year of Publication: 2002

Link to the Ovid Full Text or citation:
Click here for full text options

95.

The effect of sunscreen on melanoma risk.

Rigel D.S.

Embase

Dermatologic Clinics. 20(4) (pp 601-606), 2002. Date of Publication: October 2002.

[Review]

AN: 35101593

The usage of sunscreens has grown dramatically worldwide over the past decade. Current data suggest that a regimen of sun protection that includes protective clothing, avoiding midday sun, and regular use of broad-spectrum high SPF sunscreen (such as practiced in Australia [19]) seems to be reducing melanoma incidence rates. This is the current recommendation of the American Academy of Dermatology and it is also the recommendation that is best supported by existing data. Except for total sun avoidance, sunscreens remain the best individual method of protection from UV-induced damage to the skin. It is hoped there will be even more definitive answers to questions related to the effectiveness of sunscreens for reducing melanoma risk as better sunscreen components are developed and as evaluations are performed in the future that overcome the problems better in existing studies.

PMID: 12380047 [https://www.ncbi.nlm.nih.gov/pubmed/?term=12380047]

Status: Embase

Institution: (Rigel) Ronald O. Perelman Department of Dermatology, New York University Medical Center, 35 East 35th Street, NY 10016, United States

Publisher: W.B. Saunders (Independence Square West, Philadelphia PA 19106-3399, United States)

Year of Publication: 2002

Link to the Ovid Full Text or citation:
Click here for full text options

96.

A dermatologist's perspective on the final sunscreen monograph.

Draelos Z.D.

Embase
Journal of the American Academy of Dermatology. 44(1) (pp 109-110), 2001. Date of Publication: 2001.

[Short Survey]

AN: 32110572

The final sunscreen monograph, released on May 21, 1999, defined the upper limit for sun protection factor rating to 30+, revised the list of accepted active agents allowed in sunscreens, and changed the permissible wording of product labeling. These changes are important to the dermatologist who uses sunscreens as part of skin cancer prevention.

PMID: 11148485 [https://www.ncbi.nlm.nih.gov/pubmed/?term=11148485]

Status: Embase

Institution: (Draelos) Department of Dermatology, Wake Forest University, School of Medicine, United States

Publisher: Mosby Inc. (11830 Westline Industrial Drive, St. Louis MO 63146, United States)

Year of Publication: 2001

Link to the Ovid Full Text or citation:
Click here for full text options

97.

Modern approaches to photoprotection.

DeBuys H.V., Levy S.B., Murray J.C., Madey D.L., Pinnell S.R.

Embase
Dermatologic Clinics. 18(4) (pp 577-590), 2000. Date of Publication: 2000.

[Article]

AN: 30807120

UV light reacts with skin to produce undesirable changes, including photoaging and skin cancer. Sunscreen strategies are useful for protection against UV-B and short-wave UV-A, but complete protection against long-wave UV-A has not been achieved. Because UV-A is especially efficient at generating reactive oxygen species, it is being recognized increasingly as an important cause of photoaging and skin cancer.

PMID: 11059365 [https://www.ncbi.nlm.nih.gov/pubmed/?term=11059365]

Status: Embase

Institution: (DeBuys, Levy, Murray, Pinnell) Division of Dermatology, Department of Medicine, Duke University Medical Center, Durham, NC, United States (Levy) Department of Dermatology, University of North Carolina, School of Medicine, Chapel Hill, NC, United States
(Levy) Chapel Hill Dermatology, NC, United States
(Madey) SkinCeuticals, Dallas, TX, United States

Publisher: W.B. Saunders (Independence Square West, Philadelphia PA 19106-3399, United States)

Year of Publication: 2000

98.

Quantitive systematic review of topically applied non-steroidal anti-inflammatory drugs.

Moore R.A., Tramer M.R., Carroll D., Wiffen P.J., McQuay H.J.

Embase
British Medical Journal. 316(7128) (pp 333-338), 1998. Date of Publication: 31 Jan 1998.

[Article]

AN: 28121255

Objective: To review the effectiveness and safety of topical non-steroidal anti-inflammatory drugs in acute and chronic pain conditions.
Design(s): Quantitive systematic review of randomised controlled trials. Data sources: 86 trials involving 10,160 patients.
Main Outcome Measure(s): Measures of treatment success approximating at least 50% reduction in pain, local and systemic adverse effects. Analysis at week for acute and 2 weeks for chronic conditions with relative benefit and number needed to treat.
Result(s): In acute pain conditions (soft tissue trauma, strains, and sprains) placebo controlled trials had a relative benefit of 1.7 (1.5 to 1.9), the number needed to treat was 3.9 (3.4 to 4.4). With analysis by drug (at least three trials), ketoprofen (number needed to treat 2.6), felbinac (3.0), ibuprofen (3.5), and piroxicam (4.2) had significant efficacy. Benzydamine and indomethacin were no different from placebo. In chronic pain conditions (osteoarthritis, tendinitis) placebo controlled trials had a relative benefit of 2.0 (1.5 to 2.7); the number needed to treat was 3.1 (2.7 to 3.8). Small trials (< 40 treated patients) exaggerated effectiveness of topical non-steroidals by 33% in acute conditions but not in chronic conditions. There was no relation between trial quality and treatment effect. In both acute and chronic pain local and systemic adverse events and withdrawal from the study related to the drug had a low incidence and were no different from placebo.
Conclusion(s): Topical non-steroidal anti-inflammatory drugs are effective in relieving pain in acute and chronic conditions.

Status: Embase

Institution: (Moore, Tramer, Carroll, Wiffen, McQuay) Pain Research and Nuffield Department of Anaesthetics, University of Oxford, the Churchill, Oxford Radcliffe Hospital, Headington, Oxford OX3 7LJ, United Kingdom

Publisher: BMJ Publishing Group

Year of Publication: 1998

99.

Is there tissue penetration after application of topical salicylate formulations? [2].

Cross S.E., Anderson C., Thompson M.J., Roberts M.S.

Embase
Lancet. 350(9078) (pp 636), 1997. Date of Publication: 30 Aug 1997.

[Article]

AN: 27367800

PMID: 9288049 [https://www.ncbi.nlm.nih.gov/pubmed/?term=9288049]

Status: Embase

Institution: (Cross, Thompson, Roberts) Department of Medicine, Princess Alexandra Hospital, Brisbane, QLD 4102, Australia (Anderson) Department of Dermatology, University Hospital, Linkoping, Sweden

Publisher: Elsevier B.V.

Year of Publication: 1997

Link to the Ovid Full Text or citation:
Click here for full text options

100.

Techniques for measuring in vitro release from semisolids.

Zatz J.L., Segers J.D.

Embase

Dissolution Technologies. 5(1) (pp 3-17), 1998. Date of Publication: February 1998.

[Article]

AN: 609464954

The SUPAC-SS guidance, which governs sca/e-up and post-approval changes for sent isolids, requires in vitro release da tit in certain instances of change in the amount of an excipient, batch size or manufacturing equipment, process or site. 1'he kinetics of diffusion of an active ingredient through a semisolid into a liquid sink (the receptor) are measured: an inert, porous membrane physically separates the tiro phases. Several commercial instruments, some of which incorporate automated transfer to an analytical instrument, are available. The principal experimental decisions involve selection of temperature, membrane, receptor and timing of samples. These should be chosen to minimize undesired interactions and make diffusion through the semisolid rate-limiting so that the intrinsic release is measured. Data treatment involves plotting the amount released against the square root of time and using the slope of the linear plot as an index. Release profiles may be altered by certain changes in manufacturing or formulation.

Status: Embase

Institution: (Zatz, Segers) Rutgers College of Pharmacy, Pisctaway, NJ, United States

Publisher: Dissolution Technologies Inc (9 YORKRIDGE TRAIL, HOCKESSIN, DE 19707-9633, United States)

Year of Publication: 1998

101.

Topical agents in the treatment of rheumatic disorders.

Rosenstein E.D.

Embase
Rheumatic Disease Clinics of North America. 25(4) (pp 899-918), 1999. Date of Publication: 1999.

[Review]

AN: 29526288

Topical drug delivery may be the optimal route for the treatment of localized musculoskeletal disorders because higher drug concentrations can be achieved at the sites of clinical significance. The rationale for the use of topical salicylates and other nonsteroidal anti-inflammatory drugs (NSAIDs) in the treatment of soft-tissue rheumatic complaints and osteoarthritis is reviewed. Topical capsaicin offers another potentially beneficial therapy for the treatment of osteoarthritis of selected joints. Although there are extensive, uncontrolled experiences with DMSO that suggests its effectiveness in the treatment of musculoskeletal disorders, controlled trials yield conflicting results. The basis for the use of physical modalities such as phonophoresis and iontophoresis to improve topical drug efficacy is summarized.

PMID: 10573765 [https://www.ncbi.nlm.nih.gov/pubmed/?term=10573765]

Status: Embase

Institution: (Rosenstein) Arthritis and Rheumatic Dis. Center, Saint Barnabas Medical Center, 200 South Orange Avenue, Livingston, NJ 07039, United States

Publisher: W.B. Saunders (Independence Square West, Philadelphia PA 19106-3399, United States)

Year of Publication: 1999

Link to the Ovid Full Text or citation:
Click here for full text options

102.

Withdrawal of chlormezanone-containing products.

Mehta U.

Embase
South African Medical Journal. 89(2) (pp 137), 1999. Date of Publication: 1999.

[Short Survey]

AN: 29126802

PMID: 10191862 [https://www.ncbi.nlm.nih.gov/pubmed/?term=10191862]

Status: Embase

Institution: (Mehta) Medicines Control Council, Department of Health Pretoria, South Africa

Publisher: South African Medical Association (Private Bag X1, Pinelands 7430, South Africa)

Year of Publication: 1999

Link to the Ovid Full Text or citation:
Click here for full text options

103.

How not to get burned: New rules for sunscreens.

Anonymous

Embase
Consultant. 39(7) (pp 2066-2068), 1999. Date of Publication: 1999.

[Short Survey]

AN: 29390036

Status: Embase

Publisher: Cliggott Publishing Co. (330 Boston Post Road, Box 4027, Darien CT 06820-4027, United States)

Year of Publication: 1999

Link to the Ovid Full Text or citation:
Click here for full text options

104.

Self promotion of deep tissue penetration and distribution of methylsalicylate after topical application.

Cross S.E., Megwa S.A., Benson H.A.E., Roberts M.S.

Embase
Pharmaceutical Research. 16(3) (pp 427-433), 1999. Date of Publication: 1999.

[Article]

AN: 29162102

Purpose. To determine how changes in cutaneous blood flow induced in- vivo by methylsalicylate (MESA), compared to non-rubefacient triethanolamine salicylate (TSA), affected topical salicylate absorption and distribution, and to assess formulation therapeutic potential by comparing tissue concentrations to published antiinflammatory concentrations. Methods. Flux of salicylate from MeSA and TSA formulations applied to full-thickness rat skin was determined using in vitro diffusion cells. Anaesthetised rats were then used to quantify salicylate concentrations in plasma and tissues underlying the application site for the two formulations over a 6h period. In vitro and in vivo absorption profiles were then compared and the effect of MeSA on cutaneous blood flow assessed. Results. In vitro flux of salicylate from the MeSA formulation was 40% higher, though after correcting for differences in formulation concentrations the ratio of permeability coefficients was reversed. Contrary to the in vitro predictions, in vivo tissue and plasma concentrations of salicylate in rats rose rapidly in the first 1 hr and were more than the predicted 1.4-fold higher for MESA. This

effect was mirrored by the increase in blood flow induced by MeSA in human cutaneous vessels and that reported in the literature. Potential therapeutic levels were not seen below superficial muscle layers. Conclusions. Direct tissue penetration of salicylate occurs below application sites from both MeSA and TSA formulations. Tissue concentrations of MeSA were higher than predicted due to its rapid distribution in the blood.

PMID: 10213375 [https://www.ncbi.nlm.nih.gov/pubmed/?term=10213375]

Status: Embase

Institution: (Cross, Megwa) Department of Medicine, University of Queensland, Princess Alexandra Hospital, Brisbane, QLD 4102, Australia (Benson, Roberts) School of Pharmacy, University of Queensland, Brisbane, QLD 4072, Australia

Publisher: Springer New York (233 Springer Street, New York NY 10013-1578, United States)

Year of Publication: 1999

105.

Topical penetration of commercial salicylate esters and salts using human isolated skin and clinical microdialysis studies.

Cross S.E., Anderson C., Roberts M.S.

Embase
British Journal of Clinical Pharmacology. 46(1) (pp 29-35), 1998. Date of Publication: 1998.

[Article]

AN: 28308421

Aims: The penetration of active ingredients from topically applied anti- inflammatory pharmaceutical products into tissues below the skin is the basis of their therapeutic efficacy.

There is still controversy as to whether these agents are capable of direct penetration by diffusion through the tissues or whether redistribution in the systemic circulation is responsible for their tissue deposition below the application site.
Method(s): The extent of direct penetration of salicylate from commercial ester and salt formulations into the dermal and subcutaneous tissue of human volunteers was determined using the technique of cutaneous microdialysis. We also examined differences in the extent of hydrolysis of the methylester of salicylate applied topically in human volunteers and in vitro skin diffusion cells using full-thickness skin and epidermal membranes.
Result(s): The present study showed that whilst significant levels of salicylate could be detected in the dermis and subcutaneous tissue of volunteers treated with the methylsalicylate formulation, negligible levels of salicylate were seen following application of the triethanolamine salicylate formulation. The tissue levels of salicylate from the methylsalicylate formulation were approx. 30-fold higher than the plasma concentrations.
Conclusion(s): The absorption and tissue concentration profiles for the commercial methylsalicylate formulation are indicative of direct tissue penetration and not solely redistribution by the systemic blood supply.

PMID: 9690946 [https://www.ncbi.nlm.nih.gov/pubmed/?term=9690946]

Status: Embase

Institution: (Cross, Roberts) Department of Medicine, University of Queensland, Princess Alexandra Hospital, Brisbane, QLD 4102, Australia (Anderson) Department of Dermatology, University Hospital, Linkoping, Sweden

Publisher: Blackwell Publishing Ltd (9600 Garsington Road, Oxford OX4 2XG, United Kingdom)

Year of Publication: 1998

Link to the Ovid Full Text or citation:
Click here for full text options

106.

Effectiveness of a single topical application of 10% trolamine salicylate cream in the symptomatic treatment of osteoarthritis.

Rothacker D.Q., Lee I., Littlejohn III T.W.

Embase
Journal of Clinical Rheumatology. 4(1) (pp 6-12), 1998. Date of Publication: February 1998.

[Article]

AN: 28138679

This study was designed to evaluate the effectiveness in relief of pain and rigidity of a 10% trolamine salicylate cream compared with a placebo cream identical in smell and appearance, for subjects with osteoarthritis in their hands. This was a one-application, randomized, double-blind, placebo- controlled, parallel study conducted in 81 patients. Pain and stiffness were assessed in the morning upon subjects' awakening (baseline) and at 30, 45, and 120 rain after a 4-min rubbing application. Analgesic response was determined using the sum of pain intensity differences (SPID) and the sum of stiffness intensity differences (SSID); the sum across the observation points derived from a pain/stiffness rating scale. Trolamine salicylate was significantly superior to the placebo in improving SPID (p = 0.0492) and in improving SSID scores for both hands (p = 0.0283). Treatment differences in absolute pain and stiffness scores were significant (p <= 0.05) at 45 min after application. A 10% trolamine salicylate cream was shown to be safe and effective for the temporary relief of minor pain and stiffness associated with osteoarthritis in the hands. This formulation has no smell or counter- irritating properties; patient acceptability was good.

Status: Embase

Institution: (Rothacker) SDA Entpr. Slim Fast Nutr. Inst., New York, NY, United States (Lee) Biostatistical Services, Short Hills, NJ, United States
(Littlejohn III) Piedmont Research Associates, Winston-Salem, NC, United States
(Rothacker) SDA Entpr. Slim Fast Nutr. Inst., 767 Third Avenue, New York, NY 10017, United States

Publisher: Lippincott Williams and Wilkins (351 West Camden Street, Baltimore MD 21201-2436, United States)

Year of Publication: 1998

Link to the Ovid Full Text or citation:
Click here for full text options

107.

Phonophoresis: A literature review.

Zambito A., Castellani G., Leso P., Campacci R.

Embase
Europa Medicophysica. 33(2) (pp 103-107), 1997. Date of Publication: 1997.

[Review]

AN: 27297161

Studies of Phonophoresis are reviewed. Previous clinical studies are of the retrospective type, whereas human and animal experiments compare drugs and types of media. There is still uncertainty with regard to the real effectiveness of phonophoresis transdermal penetration of drugs.

Status: Embase

Institution: (Zambito, Castellani, Leso, Campacci) Riabilitazione Ortopedica COC, 37067 Valeggio sul Mincio (Verona), Italy

Publisher: Edizioni Minerva Medica S.p.A. (Corso Bramante 83-85, Torino 10126, Italy)

Year of Publication: 1997

Link to the Ovid Full Text or citation:
Click here for full text options

108.

Serum concentrations of salicylic acid following topically applied salicylate derivatives.

Morra P., Bartle W.R., Walker S.E., Lee S.N., Bowles S.K., Reeves R.A.

Embase
Annals of Pharmacotherapy. 30(9) (pp 935-940), 1996. Date of Publication: September 1996.

[Article]

AN: 26295242

OBJECTIVE: To compare the rate and extent of systemic salicylate absorption following single and multiple applications of two topically applied analgesics, one containing methyl salicylate and the other containing trolamine salicylate. DESIGN:Two-period, two-treatment, randomized, crossover, multiple-dose study in healthy men and women volunteers. PARTICIPANTS: Six men and six women volunteers, 21-44 years of age. INTERVENTIONS: Subjects applied 5 g of an ointment containing 12.5% methyl salicylate twice daily for 4 days (8 doses) or a cream containing trolamine 10% twice daily for two doses, to a 10-cm2 area on the thigh. Treatment order and leg (right or left) were assigned randomly. Subjects were crossed over to the alternate treatment on the other leg after a minimum washout period of 7 days. MAIN OUTCOME MEASURES: The total amount of salicylate recovered in the urine during two dosing intervals (24 hours) on each study day, relative to the applied dose, was used to calculate the bioavailability of each product. Mean standard pharmacokinetic parameters including area under the curve, maximum concentration (C(max)), time to maximum concentration, and minimum concentrations at steady-state were determined from serum concentrations. Serum concentrations were fit to three pharmacokinetic models and the suitability of each model was evaluated. Estimate of absorption rate constant, clearance, volume, and fraction absorbed on day 1 were estimated by using the best-fitting model. RESULT(S): Salicylic acid could not be detected in serum after trolamine application. However, concentrations between 0.31 and 0.91 mg/L were detected within 1 hour of the first application of methyl salicylate and C(max) between 2 and 6 mg/L were observed following the seventh application on day 4. Both the extent and rate of absorption changed after the first 24 hours. The absorption rate constant increased significantly from the first to the seventh dose (first dose absorption rate constant: 0, 16 h-1; seventh dose: 0.28 h-1; $p < 0.035$). Urinary recovery of total salicylate (salicylic acid and principal metabolites of salicylic acid) during the first 24 hours of the methyl salicylate phase averaged 175.2 mg, exceeding the 6.9 mg ($p < 0.05$) recovered during the trolamine phase. The recovery of salicylate in the urine in the first 24 hours after application of methyl salicylate was significantly greater than the 1.4% recovered after application of trolamine ($p < 0.05$). Furthermore, the fraction of

methyl salicylate recovered in the urine increased significantly from 15.5% on day 1 to approximately 22% on the second, third, and fourth days.
CONCLUSION(S): A considerable amount of salicylic acid may be absorbed through the skin after topical application of methyl salicylate products and this may increase with multiple applications. Caution is warranted in patients for whom systemic salicylate may be hazardous or problematic.

PMID: 8876850 [https://www.ncbi.nlm.nih.gov/pubmed/?term=8876850]

Status: Embase

Institution: (Morra) Department of Pharmacy, Sunnybrook Health Science Centre, University of Toronto, Toronto, Ont., Canada (Morra) St Mary's Hospital, Leonardtown, MD, United States
(Bartle, Walker, Lee, Bowles) Department of Pharmacy, Sunnybrook Health Science Centre, Canada
(Bartle, Walker, Bowles) University of Toronto, Canada
(Reeves) Division of Clinical Pharmacology, Department of Medicine, Sunnybrook Health Science Centre, Canada
(Reeves) Dept. of Cardiovasc. Clin. Research, Bristol-Myers Squibb Res. Institute, Princeton, NJ, United States
(Walker) Department of Pharmacy, Sunnybrook Health Science Centre, 2075 Bayview Ave, North York, Ont. M4N 3M5, Canada

Publisher: Harvey Whitney Books Company (8044 Montgomery Road, Suite 415, Cincinnati OH 45236, United States)

Year of Publication: 1996

Link to the Ovid Full Text or citation:
Click here for full text options

109.

Sunscreens: The ounce of prevention.

Wentzell J.M.

Embase
American Family Physician. 53(5) (pp 1713-1719), 1996. Date of Publication: April 1996.

[Review]

AN: 26119782

Sun exposure is linked to visible signs of skin aging, skin cancer, photodermatoses, exacerbation of systemic disease and photoallergic, as well as phototoxic, drug eruptions. Sunscreens very considerably in their ability to protect patients from exposure to ultraviolet light and its effects. Inappropriate choice and use of sunscreen products can lead to worse problems than using no sunscreen at all. Controversies about sunscreen include adequate level of sun protection factor, appropriate age of users, and whether use of sunscreen products can prevent skin cancer. Instructing patients in how to select end use sunscreen can help prevent or mitigate a variety of cutaneous end systemic diseases.

PMID: 8623697 [https://www.ncbi.nlm.nih.gov/pubmed/?term=8623697]

Status: Embase

Institution: (Wentzell) Billings Clinic, Billings, MT, United States

Publisher: American Academy of Family Physicians (11400 Tomahawk Creek Parkway, Suite 440, Leawood KS 66211, United States)

Year of Publication: 1996

Link to the Ovid Full Text or citation:
Click here for full text options

110.

Percutaneous absorption of salicylates from some commercially available topical products containing methyl salicylate or salicylate salts in rats.

Megwa S.A., Benson H.A.E., Roberts M.S.

Embase
Journal of Pharmacy and Pharmacology. 47(11) (pp 891-896), 1995. Date of Publication: 1995.

[Article]

AN: 26022470

Studies to determine the extent of local tissue penetration of topically applied, commercially available salicylate esters and salts were conducted in male Wistar rats. The salicylate concentration in plasma, tissues underlying the site of drug application, and similar tissues on the contralateral (control) side were measured. The plasma and tissue salicylate levels suggest that direct penetration of salicylate was predominant to the top muscle level on the treated site. Results also suggest that the drugs were first absorbed into the bloodstream and subsequently distributed to both the deeper tissues on the treated site and the contralateral tissues. The topical application of formulations of ester methyl salicylate and salts triethanolamine salicylate and diethylamine salicylate containing comparable salicylate concentrations yielded similar salicylate concentrations in the various tissues. The salicylate concentrations in the deeper tissues approached concentrations observed in the contralateral tissues suggesting that salicylate present in these tissues was due to the systemic blood supply.

PMID: 8708981 [https://www.ncbi.nlm.nih.gov/pubmed/?term=8708981]

Status: Embase

Institution: (Megwa, Benson, Roberts) Department of Medicine, The University of Queensland, Brisbane, QLD 4072, Australia

Publisher: Pharmaceutical Press (1 Lambeth High Street, London SE1 7JN, United Kingdom)

Year of Publication: 1995

111.

A clinical trial of topical 10% trolamine salicylate in osteoarthritis.

Rothacker D., Difigilo C., Lee I.

Embase
Current Therapeutic Research - Clinical and Experimental. 55(5) (pp 584-597), 1994. Date of Publication: 1994.

[Article]

AN: 24172984

This short-term, double-blind, placebo-controlled, crossover study evaluated the effectiveness of 10% trolamine salicylate in a cream base as a topical analgesic compared with placebo. Fifty patients with pain and stiffness because of osteoarthritis in their hands participated in the study; 49 patients completed the study. Patients rated their pain and stiffness in the morning on awakening, and at 15, 30, 45, and 120 minutes after application of their study cream. Although the phases of this crossover study were separated by 1 week, a consistent period effect occurred. Because of these residual effects, the statistical results of period 1 become our focus as this period was free of carryover and period effects. A trend in favor of trolamine salicylate was seen 30 minutes following application of the study drug; at 45 minutes, use of trolamine salicylate was clearly better than placebo in achieving pain relief (P = 0.0401; intent-to-treat). Two hours following a single application of the study drug, much of the drug effect had worn off. Trolamine salicylate was better (marginally significant) than placebo in time to peak pain relief (P = 0.0674; intent-to-treat), in disappearance of pain (P = 0.0435; intent-to-treat), and overall trend analysis. Stiffness relief was attained significantly earlier (35 minutes compared with 58 minutes) in the group treated with trolamine salicylate compared with placebo (P = 0.0368; per protocol). No significant adverse effects were reported.

Status: Embase

Institution: (Rothacker) SDA Enterprises, Inc., West Palm Beach, FL, United States
(Difigilo) Essex Testing Clinic, Inc., Verona, NJ, United States
(Lee) Biostatistical Services, Short Hills, NJ, United States

(Rothacker) SDA Enterprises, Inc., 222 Lakeview Avenue, West Palm Beach, FL 33401, United States

Publisher: Excerpta Medica Inc. (105 Raider Blvd, Suite 101, Hillsborough NJ 08844, United States)

Year of Publication: 1994

Link to the Ovid Full Text or citation:
Click here for full text options

112.

OTC drug use and blood glucose control.

Baker D.E.

Embase
U.S. Pharmacist. 18(1) (pp 65-66+68+70-72+110), 1993. Date of Publication: 1993.

[Review]

AN: 23195786

Status: Embase

Institution: (Baker) Drug Information Center, College of Pharmacy, Washington State University, Spokane, WA, United States

Publisher: Jobson Publishing Corporation (100 Avenue of the Americas, New York NY 10013-1678, United States)

Year of Publication: 1993

Link to the Ovid Full Text or citation:
Click here for full text options

113.

Issues in contemporary drug delivery part VII: Treatment of rheumatoid arthritis.

Chotidiloke Sr. C., Elkin S.P., Banakar U.V.

Embase
Journal of Pharmacy Technology. 9(2) (pp 52-62), 1993. Date of Publication: 1993.

[Article]

AN: 23131527

Objective: To provide an overview of rheumatoid arthritis (RA) and the medications presently being used to treat the disease.

Data Sources: References have been selected from published articles, monographs, manufacturers' product information, textbooks on therapeutics of rheumatic diseases, and specific computerised databases such as DRUGDEX. Study Selection: Studies that establish the pharmacokinetics of the various drugs have been included, as have comparative studies of the various agents. Studies that gave specifics concerning the use of the various agents in the elderly were given priority in selection. Monographs from both United States Pharmacopeia Dispensing Information and American Hospital Formulary Service Drug Information '92 were used to ensure consistency in dosing and pharmacokinetic data.

Data Synthesis: A variety of medications are used to treat RA, and are classified according to their ability to alleviate the inflammatory process and symptomatology of the disease, or to actually slow down or halt the progression of the disease process itself. The long-established pyramidal approach to therapy is presently being challenged so as to employ the slow-acting or disease-modifying agents earlier in the process.
Conclusion(s): A wide variety of medications are presently available for treating RA. As the pathogenesis of the disease becomes better defined, it is hoped that less-toxic and more-specific and -effective therapies will become available. Medications remain the cornerstone of therapy; however, patient education, rest, and exercise are equally important.

Status: Embase

Institution: (Chotidiloke Sr., Elkin, Banakar) School of Pharmacy, Allied Health Professions, Creighton University, Omaha, NE, United States

Publisher: Harvey Whitney Books Company (8044 Montgomery Road, Suite 415, Cincinnati OH 45236, United States)

Year of Publication: 1993

Link to the Ovid Full Text or citation:
Click here for full text options

114.

Sunscreens and insect repellents.

Anonymous

Embase
Canadian Pharmaceutical Journal. 126(5) (pp 250-251+255), 1993. Date of Publication: 1993.

[Short Survey]

AN: 23217510

Status: Embase

Publisher: Canadian Pharmacists Association (1785 Alta Vista Drive, Ottawa ON K1G 3Y6, Canada)

Year of Publication: 1993

Link to the Ovid Full Text or citation:
Click here for full text options

115.

Sports-related allergic dermatitis.

Fisher A.A.

Embase
Cutis. 50(2) (pp 95-97), 1992. Date of Publication: 1992.

[Review]

AN: 22260415

PMID: 1511624 [https://www.ncbi.nlm.nih.gov/pubmed/?term=1511624]

Status: Embase

Institution: (Fisher) 14 East 82nd Street, New York, NY 10028, United States

Publisher: Quadrant Healthcom Inc. (7 Century Drive, Suite 302, Parsippany NJ 07054-4609, United States)

Year of Publication: 1992

Link to the Ovid Full Text or citation:
Click here for full text options

116.

Sports injuries.

Nykamp D.

Embase
U.S. Pharmacist. 17(4) (pp 34-36+38-39+43-44+46-47+51-52+55), 1992. Date of Publication: 1992.

[Review]

AN: 23171941

Status: Embase

Institution: (Nykamp) Pharmacy Practice, Mercer Univ. Southern Sch. of Pharm., Atlanta, GA, United States

Publisher: Jobson Publishing Corporation (100 Avenue of the Americas, New York NY 10013-1678, United States)

Year of Publication: 1992

117.

Relative transmission of ultrasound by media customarily used for phonophoresis.

Cameron M.H., Monroe L.G.

Embase
Physical Therapy. 72(2) (pp 142-148), 1992. Date of Publication: 1992.

[Article]

AN: 22061232

The purpose of this study was to determine the relative transmission of ultrasound by the media commonly used by physical therapists to apply phonophoresis. The relative transmission of ultrasound energy through various phonophoresis media was compared with that of degassed water, which is the ideal standard. Transmission was assessed by placing a thin layer of the test medium on the transducer of a therapeutic ultrasound unit and measuring delivery of ultrasound with an ultrasound power meter. The media evaluated produced two significantly different groups of transmission results: (1) transmission greater than 80% of that of water and (2) transmission less than 40% of that of water. Media that

optimize the therapeutic efficacy of phonophoresis in both clinical and experimental settings are discussed.

PMID: 1549636 [https://www.ncbi.nlm.nih.gov/pubmed/?term=1549636]

Status: Embase

Institution: (Cameron, Monroe) 6131 Thornhill Dr, Oakland, CA 94611, United States

Publisher: American Physical Therapy Association (1111 North Fairfax Street, Alexandria VA 22314, United States)

Year of Publication: 1992

Link to the Ovid Full Text or citation:
Click here for full text options

118.

Back to school health issues.

Gossel T.A.

Embase
U.S. Pharmacist. 17(9) (pp 18-26+79), 1992. Date of Publication: 1992.

[Review]

AN: 23170269

Status: Embase

Institution: (Gossel) Department of Clinical Pharmacy, Ohio Northern University, Ada, OH, United States

Publisher: Jobson Publishing Corporation (100 Avenue of the Americas, New York NY 10013-1678, United States)

Year of Publication: 1992

Link to the Ovid Full Text or citation:
Click here for full text options

119.

Letter to the editor [1].

Cameron M.H., Perrin D.H.

Embase
Medicine and Science in Sports and Exercise. 23(10) (pp 1213), 1991. Date of Publication: 1991.

[Letter]

AN: 21328021

Status: Embase

Institution: (Cameron, Perrin) 6131 Thornhill Drive, Oakland, CA 94611 United States

Publisher: Lippincott Williams and Wilkins (530 Walnut Street,P O Box 327, Philadelphia PA 19106-3621, United States)

Year of Publication: 1991

Link to the Ovid Full Text or citation:
Click here for full text options

120.

Warfarin and topical salicylates.

Littleton Jr. F.

Embase
Journal of the American Medical Association. 263(21) (pp 2888), 1990. Date of Publication: 1990.

[Letter]

AN: 20173157

PMID: 2338749 [https://www.ncbi.nlm.nih.gov/pubmed/?term=2338749]

Status: Embase

Publisher: American Medical Association (515 North State Street, Chicago IL 60654, United States)

Year of Publication: 1990

Link to the Ovid Full Text or citation:
Click here for full text options

121.

Controversial arthritis remedies.

Panush R.S.

Embase
Bulletin on the Rheumatic Diseases. 34(5) (pp 10 p.)), 1984. Date of Publication: 1984.

[Article]

AN: 15082025

PMID: 6400433 [https://www.ncbi.nlm.nih.gov/pubmed/?term=6400433]

Status: Embase

Year of Publication: 1984

Link to the Ovid Full Text or citation:
Click here for full text options

122.

Two double-blind comparisons of a topically applied salicylate cream and orally ingested aspirin in the relief of chronic musculoskeletal pain.

Shamszad M., Perkal M., Golden E.L., Marlin R.L.

Embase
Current Therapeutic Research - Clinical and Experimental. 39(4) (pp 470-479), 1986. Date of Publication: 1986.

[Article]

AN: 17027287

Two separate double-blind studies comparing orally ingested aspirin to topically applied trolamine salicylate (TEAS) in a neutral cream base were conducted over a seven-day period in a total of 90 patients with chronic arthritic and/or musculoskeletal pain. By several criteria, including both patient and physician evaluations, topical TEAS was demonstrated to be comparable to oral aspirin in relieving pain of varying severity in different body locations. TEAS was superior to oral aspirin in time of onset, patient acceptance, and incidence of adverse effects.

Status: Embase

Institution: (Shamszad, Perkal, Golden, Marlin) PharmaKinetic Centers for Clinical Studies, Baltimore, MD United States

Year of Publication: 1986

Link to the Ovid Full Text or citation:
Click here for full text options

123.

Neutrophilic dermatosis (Sweet's syndrome). Association with a hydralazine-induced lupus syndrome.

Sequeira W., Polisky R.B., Alrenga D.P.

Embase
American Journal of Medicine. 81(3) (pp 558-560), 1986. Date of Publication: 1986.

[Article]

AN: 16003885

Neutrophilic dermatosis (Sweet's syndrome) is a condition that presents with arthritis and a skin rash. A case report is presented, and an association with hydralazine and lupus is described.

PMID: 2944382 [https://www.ncbi.nlm.nih.gov/pubmed/?term=2944382]

Status: Embase

Institution: (Sequeira, Polisky, Alrenga) Division of Rheumatology, Cook County Hospital, Chicago, IL 60612 United States

Year of Publication: 1986

Link to the Ovid Full Text or citation:
Click here for full text options

124.

External analgesics.

Ruston R.

Embase
On Continuing Practice. 12(2) (pp 2-6), 1985. Date of Publication: 1985.

[Article]

AN: 15103056

Status: Embase

Institution: (Ruston) Stratford General Hospital, Stratford, Ont. Canada

Year of Publication: 1985

Link to the Ovid Full Text or citation:
Click here for full text options

125.

Recent advences in transdermal drug delivery.

Guy R.H.

Embase
Therapeutic Research. 3(6) (pp 1031-1042), 1985. Date of Publication: 1985.

[Article]

AN: 16179383

This lecture is about transdermal drug delivery. It will be divided into two parts. The first part will deal with transdermal drug delivery for systemic therapeutic effect, and will describe a number of transdermal systems which have been developed, and which are, or soon will be used in the United States for the treatment of the systemic disease. The second part will deal with the use of transdermal drug delivery to achieve a local pharmacological effect, and some

of the ramifications of using the skin to achieve significant local concentrations of drug to relieve local discomfort.

Status: Embase

Institution: (Guy) Department of Pharmacy, University of California, San Francisco, CA 94143 United States

Year of Publication: 1985

Link to the Ovid Full Text or citation:
Click here for full text options

126.

Penetration of trolamine salicylate into the skeletal muscle of the pig.

Baldwin J.R., Carrano R.A., Imondi A.R.

Embase
Journal of Pharmaceutical Sciences. 73(7) (pp 1002-1004), 1984. Date of Publication: 1984.

[Article]

AN: 14084786

Studies to determine the extent of local tissue penetration of topically applied trolamine [14C]salicylate were conducted in domestic pigs. The preparation was applied onto a 100-cm2 shaved area of skin overlying the biceps femoris at a concentration of 0.7 mg of salicylate/cm2 to closely approximate the actual use in humans. At least 82% of the topically applied trolamine salicylate was absorbed over a 2-h period. Based on blood and muscle salicylate levels, a localization of the absorbed drug occurred in muscle underlying the treated area within 120 min. Muscle from the treated area had a concentration of salicylate that was 13 times that of blood and 49 times that of muscle taken from untreated areas. Blood samples taken from the treated area at 10, 20, and 30 min showed that salicylate levels ranged from 15.8 to 5.3 mug/g. Less than 0.5% of the applied drug was excreted in the urine during the 2-h period.

PMID: 6470939 [https://www.ncbi.nlm.nih.gov/pubmed/?term=6470939]

Status: Embase

Institution: (Baldwin, Carrano, Imondi) Adria Laboratories, Inc., Columbus, OH 43216 United States

Year of Publication: 1984

127.

Absorption of labeled triethanolamine salicylate in human and canine knee joints. II.

Rabinowitz J.L., Baker D.

Embase
Journal of Clinical Pharmacology. 24(11-12) (pp 532-539), 1984. Date of Publication: 1984.

[Article]

AN: 15180278

The transdermal absorption by tissues of salicylate from triethanolamine salicylate (TEA/S) ointment applied to canine and human skin was shown to be consistent, significant, and reproducible. Salicylate levels were measured using thin-layer chromatography, nuclear magnetic resonance, and radiochemistry. Absorption was directly proportional to the concentrations of the active ingredient in the ointment, up to the 10 per cent preparation. Tissue salicylate levels were not influenced by the sex of the canine subjects. In humans, the activity of the patients affected both tissue levels and urinary excretion. Autoradiographic and doubly labeled studies suggest that during transdermal absorption of TEA/S, the salt may disassociate: this could permit the salicylate to have a longer transit time in the area of application.

PMID: 6334699 [https://www.ncbi.nlm.nih.gov/pubmed/?term=6334699]

Status: Embase

Institution: (Rabinowitz, Baker) Radioisotope Research Center, Veterans Administration Medical Center, University of Pennsylvania, University and Woodland Avenues, Philadelphia, PA 19104 United States

Year of Publication: 1984

128.

Comparative tissue absorption of oral 14C-aspirin and topical triethanolamine 14C-salicylate in human and canine knee joints.

Rabinowitz J.L., Feldman E.S., Weinberger A., Schumacher H.R.

Embase
Journal of Clinical Pharmacology. 22(1) (pp 42-48), 1982. Date of Publication: 1982.

[Article]

AN: 12185374

The local, articular, and systemic absorption of oral and topical salicylates was studied in dogs and humans using radioisotope techniques. Topical triethanolamine 14C-salicylate was found capable of percutaneous absorption into the knee joint and surrounding tissues. In dogs, topical salicylate application resulted in higher salicylate concentrations than oral aspirin in a number of tissues, despite lower blood levels. In patients with rheumatoid arthritis, intraarticular 14C-salicylate levels after triethanolamine 14C-salicylate cream were 60% of those obtained with oral aspirin. Four of six patients reported equal improvement in local discomfort after oral and topical salicylates. A potential role for topical salicylate cream in the treatment of localized rheumatic disorders is suggested.

PMID: 6977559 [https://www.ncbi.nlm.nih.gov/pubmed/?term=6977559]

Status: Embase

Institution: (Rabinowitz, Feldman, Weinberger, Schumacher) Div. Radioisot. Res., Arthritis-Immunol. Cent., VA Med. Cent., Univ. Pennsylvania, Philadelphia, PA 19104 United States

Year of Publication: 1982

Link to the Ovid Full Text or citation:
Click here for full text options

129.

Trolamine salicylate cream in osteoarthritis of the knee.

Algozzine G.J., Stein G.H., Doering P.L.

Embase
Journal of the American Medical Association. 247(9) (pp 1311-1313), 1982. Date of Publication: 1982.

[Article]

AN: 12175675

Twenty-five patients with symptomatic osteoarthritis (OA) of the knee were treated topically for one week with either 10% trolamine salicylate cream or placebo cream in a randomized double-blind crossover study. No significant difference was found in subjective or objective measures of pain relief between the treatment and control groups. Eight patients preferred 'active' test cream, six preferred placebo, and 11 had no preference. No side effects were reported. Topically applied 10% trolamine salicylate cream did not relieve the pain of OA of the knee any more than did placebo.

PMID: 7038182 [https://www.ncbi.nlm.nih.gov/pubmed/?term=7038182]

Status: Embase

Institution: (Algozzine, Stein, Doering) Dept. Pharm. Practice, Coll. Pharm., Univ. Florida, Gainesville, FL United States

Year of Publication: 1982

Link to the Ovid Full Text or citation:
Click here for full text options

130.

Effectiveness on mucous membranes of topically applied antipyretic analgesics.

Adriani J., Minokadeh S., Naraghi M.

Embase
Regional Anesthesia. 6(2) (pp 47-50), 1981. Date of Publication: 1981.

[Article]

AN: 12128224

Certain antipyretic analgesics are advocated for topical use to relieve acute or chronic pain. It is alleged, without scientific evidence to support the claim, that they possess local anesthetic activity. This study was undertaken to determine whether or not these ingredients possess local anesthetic activity. Using an electric current delivered from a nerve stimulator to the pain receptors at the tip of the tongue, it was found that saturated solutions of aspirin, sodium salicylate, methyl salicylate, triethanolamine salicylate, acetaminophen, phenylbutazone (Butazolidine()), and antipyrine possessed no topical anesthetic activity in contrast to benzocaine which produced a complete blockade of these pain receptors. Presumably, any pain-relieving effect with antipyretic analgesics is obtained due to a systemic action following absorption of these drugs when applied topically to mucous membranes.

Status: Embase

Institution: (Adriani, Minokadeh, Naraghi) Dep. Pharmacol. Anesthesiol., Louisiana State Med. Cent., New Orleans, LA 70140 United States

Year of Publication: 1981

Link to the Ovid Full Text or citation:
Click here for full text options

131.

A double-blind comparison of orally ingested aspirin and a topically applied salicylate cream in the relief of rheumatic pain.

Golden E.L.

Embase
Current Therapeutic Research - Clinical and Experimental. 24(5) (pp 524-529), 1978. Date of Publication: 1978.

[Article]

AN: 9035495

A double-blind comparison of orally ingested aspirin and topically applied triethanolamine salicylate (TEA) 10%, in a neutral cream base, was conducted on forty patients for the relief of rheumatic pain. During the seven-day period of the study, TEA was at least as effective as aspirin in achieving pain relief, tended to provide relief more quickly, had fewer side effects, and was less likely to lead to patients' discontinuing treatment. TEA appears to offer a superior alternative to orally ingested aspirin in the relief of pain resulting from rheumatoid conditions with less side effects and greater tolerance by patients.

Status: Embase

Institution: (Golden) 1175 West Broadway, Hewlett, N.Y. 11557 United States

Year of Publication: 1978

Link to the Ovid Full Text or citation:
Click here for full text options

132.

Euglena gracilis Extract Protects From Tobacco Smoke Carcinogen-Induced Lung Cancer by Altering Gut Microbiota Metabolome.

Upreti D, Ishiguro S, Phillips M, Nakashima A, Suzuki K, Comer J, Tamura M

Ovid MEDLINE(R) ALL
Integrative Cancer Therapies. 22:15347354231195323, 2023 Jan-Dec.

[Journal Article. Research Support, N.I.H., Extramural. Research Support, Non-U.S. Gov't]

UI: 37646331

Extracts from Euglena gracilis have been shown to prevent cancer growth in mouse models. However, the molecular mechanism of this anti-cancer activity has not been determined nor has the effect of Euglena extracts on tobacco smoke carcinogen-induced carcinogenesis. Here, we investigate the hypothesis that this anti-cancer activity is a result of changes in the intestinal microbiota induced by oral administration of the extract. We found that a Euglena gracilis water extract prevents lung tumorigenesis induced by a tobacco smoke-specific carcinogen (NNK) in mice treated either 2 weeks before or 10 weeks after NNK injection. Both of these treatment regimens are associated with significant increases in 27 microbiota metabolites found in the mouse feces, including large increases in triethanolamine, salicylate, desaminotyrosine, N-acetylserine, glycolate, and aspartate. Increases in the short-chain fatty acids (SCFAs) including acetate, propionate and butyrate are also observed. We also detected a significant attenuation of lung carcinoma cell growth through the induction of cell cycle arrest and apoptosis caused by low levels of SCFAs. This study provides strong evidence of anti-cancer activity in Euglena gracilis extracts against tobacco smoke carcinogen-induced tumorigenesis and demonstrates that this activity is linked to increased production of specific gut microbiota metabolites and the resultant induction of cell cycle arrest and apoptosis of lung carcinoma cells.

Version ID: 1

Status: MEDLINE

Author Initials: Tamura, Masaaki; ORCID: https://orcid.org/0000-0003-4863-3379

Authors Full Name: Upreti, Deepa, Ishiguro, Susumu, Phillips, Morgan, Nakashima, Ayaka, Suzuki, Kengo, Comer, Jeffrey, Tamura, Masaaki

Institution: Upreti, Deepa. Department of Anatomy & Physiology, Kansas State University College of Veterinary Medicine, Manhattan, KS, USA. Ishiguro, Susumu. Department of Anatomy & Physiology, Kansas State University College of Veterinary Medicine, Manhattan, KS, USA.
Phillips, Morgan. Department of Anatomy & Physiology, Kansas State University College of Veterinary Medicine, Manhattan, KS, USA.
Nakashima, Ayaka. Euglena Co. Ltd., Minato-ku, Tokyo, Japan.
Suzuki, Kengo. Euglena Co. Ltd., Minato-ku, Tokyo, Japan.
Comer, Jeffrey. Department of Anatomy & Physiology, Kansas State University College of Veterinary Medicine, Manhattan, KS, USA.
Tamura, Masaaki. Department of Anatomy & Physiology, Kansas State University College of Veterinary Medicine, Manhattan, KS, USA.

PMID: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10469252

Year of Publication: 2023

Link to the Ovid Full Text or citation:
Click here for full text options

133.

Safety assessment of Salicylic Acid, Butyloctyl Salicylate, Calcium Salicylate, C12-15 Alkyl Salicylate, Capryloyl Salicylic Acid, Hexyldodecyl Salicylate, Isocetyl Salicylate, Isodecyl Salicylate, Magnesium Salicylate, MEA-Salicylate, Ethylhexyl Salicylate, Potassium Salicylate, Methyl Salicylate, Myristyl Salicylate, Sodium Salicylate, TEA-Salicylate, and Tridecyl Salicylate. [Review] [320 refs]

Anonymous

Ovid MEDLINE(R) ALL
International Journal of Toxicology. 22 Suppl 3:1-108, 2003.

[Journal Article. Research Support, Non-U.S. Gov't. Review]

UI: 14617432

Salicylic Acid is an aromatic acid used in cosmetic formulations as a denaturant, hair-conditioning agent, and skin-conditioning agent--miscellaneous in a wide range of cosmetic products at concentrations ranging from 0.0008% to 3%. The Calcium, Magnesium, and MEA salts are preservatives, and Potassium Salicylate is a cosmetic biocide and preservative, not currently in use. Sodium Salicylate is used as a denaturant and preservative (0.09% to 2%). The TEA salt of Salicylic Acid is used as an ultraviolet (UV) light absorber (0.0001% to 0.75%). Several Salicylic Acid esters are used as skin conditioning agents--miscellaneous (Capryloyl, 0.1% to 1%; C12-15 Alkyl, no current use; Isocetyl, 3% to 5%; Isodecyl, no current use; and Tridecyl, no current use). Butyloctyl Salicylate (0.5% to 5%) and Hexyldodecyl Salicylate (no current use) are hair-conditioning agents and skin-conditioning agents--miscellaneous. Ethylhexyl Salicylate (formerly known as Octyl Salicylate) is used as a fragrance ingredient, sunscreen agent, and UV light absorber (0.001% to 8%), and Methyl Salicylate is used as a denaturant and flavoring agent (0.0001% to 0.6%). Myristyl Salicylate has no reported function. Isodecyl Salicylate is used in three formulations, but no concentration of use information was reported. Salicylates are absorbed percutaneously. Around 10% of applied salicylates can remain in the skin. Salicylic Acid is reported to enhance percutaneous penetration of some agents (e.g., vitamin A), but not others (e.g., hydrocortisone). Little acute toxicity (LD(50) in rats; >2 g/kg) via a dermal exposure route is seen for Salicylic Acid, Methyl Salicylate, Tridecyl Salicylate, and Butyloctyl Salicylate. Short-term oral, inhalation, and parenteral exposures to salicylates sufficient to produce high blood concentrations are associated primarily with liver and kidney damage. Subchronic dermal exposures to undiluted Methyl Salicylate were associated with kidney damage. Chronic oral exposure to Methyl Salicylate produced bone lesions as a function of the level of exposure in 2-year rat studies; liver damage was seen in dogs exposed to 0.15 g/kg/day in one study; kidney and liver weight increases in another study at the same exposure; but no liver or kidney abnormalities in a study at 0.167 g/kg/day. Applications of Isodecyl, Tridecyl, and Butyloctyl Salicylate were not irritating to rabbit skin, whereas undiluted Ethylhexyl Salicylate produced minimal to mild irritation. Methyl Salicylate at a 1% concentration with a 70% ethanol vehicle were irritating, whereas a 6% concentration in polyethylene glycol produced little or no irritation. Isodecyl Salicylate, Methyl Salicylate, Ethylhexyl (Octyl) Salicylate, Tridecyl Salicylate, and Butyloctyl Salicylate were not ocular irritants. Although Salicylic Acid at a concentration of 20% in

acetone was positive in the local lymph node assay, a concentration of 20% in acetone/olive oil was not. Methyl Salicylate was negative at concentrations up to 25% in this assay, independent of vehicle. Maximization tests of Methyl Salicylate, Ethylhexyl Salicylate, and Butyloctyl Salicylate produced no sensitization in guinea pigs. Neither Salicylic Acid nor Tridecyl Salicylate were photosensitizers. Salicylic Acid, produced when aspirin is rapidly hydrolyzed after absorption from the gut, was reported to be the causative agent in aspirin teratogenesis in animals. Dermal exposures to Methyl Salicylate, oral exposures to Salicylic Acid, Sodium Salicylate, and Methyl Salicylate, and parenteral exposures to Salicylic Acid, Sodium Salicylate, and Methyl Salicylate are all associated with reproductive and developmental toxicity as a function of blood levels reached as a result of exposure. An exposure assessment of a representative cosmetic product used on a daily basis estimated that the exposure from the cosmetic product would be only 20% of the level seen with ingestion of a "baby" aspirin (81 mg) on a daily basis. Studies of the genotoxic potential of Salicylic Acid, Sodium Salicylate, Isodecyl Salicylate, Methyl Salicylate, cosmetic product would be only 20% of the level seen with ingestion of a "baby" aspirin (81 mg) on a daily basis. Studies of the genotoxic potential of Salicylic Acid, Sodium Salicylate, Isodecyl Salicylate, Methyl Salicylate, Ethylhexyl (Octyl) Salicylate, Tridecyl Salicylate, and Butyloctyl Salicylate were generally negative. Methyl Salicylate, in a mouse skin-painting study, did not induce neoplasms. Likewise, Methyl Salicylate was negative in a mouse pulmonary tumor system. In clinical tests, Salicylic Acid (2%) produced minimal cumulative irritation and slight or no irritation(1.5%); TEA-Salicylate (8%) produced no irritation; Methyl Salicylate (>12%) produced pain and erythema, a 1% aerosol produced erythema, but an 8% solution was not irritating; Ethylhexyl Salicylate (4%) and undiluted Tridecyl Salicylate produced no irritation. In atopic patients, Methyl Salicylate caused irritation as a function of concentration (no irritation at concentrations of 15% or less). In normal skin, Salicylic Acid, Methyl Salicylate, and Ethylhexyl (Octyl) Salicylate are not sensitizers. Salicylic Acid is not a photosensitizer, nor is it phototoxic. Salicylic Acid and Ethylhexyl Salicylate are low-level photoprotective agents. Salicylic Acid is well-documented to have keratolytic action on normal human skin. Because of the possible use of these ingredients as exfoliating agents, a concern exists that repeated use may effectively increase exposure of the dermis and epidermis to UV radiation. It was concluded that the prudent course of action would be to advise the cosmetics industry that there is a risk of increased UV radiation damage with the use of any exfoliant, including Salicylic Acid and the listed salicylates, and that steps need to be taken to formulate cosmetic products with these ingredients as exfoliating agents so as not to increase sun sensitivity, or when increased sun sensitivity would be expected, to include directions for the daily use of sun protection. The available data were not sufficient to establish a limit on concentration of these ingredients, or to identify the minimum pH of formulations containing these ingredients, such that no skin irritation would occur, but it was recognized that it is

possible to formulate cosmetic products in a way such that significant irritation would not be likely, and it was concluded that the cosmetics industry should formulate products containing these ingredients so as to be nonirritating. Although simultaneous use of several products containing Salicylic Acid could produce exposures greater than would be seen with use of baby aspirin (an exposure generally considered to not present a reproductive or developmental toxicity risk), it was not considered likely that consumers would simultaneously use multiple cosmetic products containing Salicylic Acid. Based on the available information, the Cosmetic Ingredient Review Expert Panel reached the conclusion that these ingredients are safe as used when formulated to avoid skin irritation and when formulated to avoid increasing the skin's sun sensitivity, or, when increased sun sensitivity would be expected, directions for use include the daily use of sun protection. [References: 320]

Version ID: 1

Status: MEDLINE

Clinical Trial Number: Cosmetic Ingredient Review Expert Panel

Year of Publication: 2003

Link to the Ovid Full Text or citation:
Click here for full text options

134.

Self promotion of deep tissue penetration and distribution of methylsalicylate after topical application.

Cross SE, Megwa SA, Benson HA, Roberts MS

Ovid MEDLINE(R) ALL
Pharmaceutical Research. 16(3):427-33, 1999 Mar.

[Comparative Study. Journal Article. Research Support, Non-U.S. Gov't]

UI: 10213375

PURPOSE: To determine how changes in cutaneous blood flow induced in-vivo by methylsalicylate (MeSA), compared to non-rubefacient triethanolamine salicylate (TSA), affected topical salicylate absorption and distribution, and to assess formulation therapeutic potential by comparing tissue concentrations to published antiinflammatory concentrations.

METHODS: Flux of salicylate from MeSA and TSA formulations applied to full-thickness rat skin was determined using in vitro diffusion cells. Anaesthetised rats were then used to quantify salicylate concentrations in plasma and tissues underlying the application site for the two formulations over a 6h period. In vitro and in vivo absorption profiles were then compared and the effect of MeSA on cutaneous blood flow assessed.

RESULTS: In vitro flux of salicylate from the MeSA formulation was 40% higher, though after correcting for differences in formulation concentrations the ratio of permeability coefficients was reversed. Contrary to the in vitro predictions, in vivo tissue and plasma concentrations of salicylate in rats rose rapidly in the first 1 hr and were more than the predicted 1.4-fold higher for MeSA. This effect was mirrored by the increase in blood flow induced by MeSA in human cutaneous vessels and that reported in the literature. Potential therapeutic levels were not seen below superficial muscle layers.

CONCLUSIONS: Direct tissue penetration of salicylate occurs below application sites from both MeSA and TSA formulations. Tissue concentrations of MeSA were higher than predicted due to its rapid distribution in the blood.

Version ID: 1

Status: MEDLINE

Authors Full Name: Cross, S E, Megwa, S A, Benson, H A, Roberts, M S

Institution: Cross, S E. Department of Medicine, University of Queensland, Princess Alexandra Hospital, Brisbane, Australia.

Year of Publication: 1999

135.

Effect of phonophoresis on serum salicylate levels.

Oziomek RS, Perrin DH, Herold DA, Denegar CR

Ovid MEDLINE(R) ALL
Medicine & Science in Sports & Exercise. 23(4):397-401, 1991 Apr.

[Clinical Trial. Journal Article. Randomized Controlled Trial]

UI: 2056895

The purpose of this investigation was to determine the effect of ultrasound intensity and mode on serum salicylate levels following phonophoresis. Approximately 12-13 g of a salicylate product (Myoflex) was applied to the right anterior forearm of five males and two females. Randomly ordered ultrasound treatment intensities (0.0 W.cm-2; 1.5 W.cm-2, pulsed 50%; and 1.5 W.cm-2, continuous) were applied through the salicylate-containing product for a 5 min duration. A 7.0 ml blood sample was drawn from the left anterior forearm prior to each treatment and again 2 h after treatment. Analysis of variance indicated that none of the topical salicylate treatments produced an increase in serum salicylate levels. These findings suggest that there is no appreciable absorption of salicylate into the bloodstream following topical application of salicylate with or without the use of ultrasound. Since any penetration of salicylate through the skin would result in an increase in serum salicylate levels, the efficacy of phonophoresis to introduce medication into the subdermal tissue is questionable. These findings suggest that a critical review of phonophoresis in general is indicated.

Version ID: 1

Status: MEDLINE

Authors Full Name: Oziomek, R S, Perrin, D H, Herold, D A, Denegar, C R

Institution: Oziomek, R S. Sports Medicine/Athletic Training Research Laboratory, University of Virginia, Charlottesville 22903.

Comments: Comment in (CIN)

Year of Publication: 1991

Link to the Ovid Full Text or citation:
Click here for full text options

136.

Effects of ultrasound and trolamine salicylate phonophoresis on delayed-onset muscle soreness.

Ciccone CD, Leggin BG, Callamaro JJ

Ovid MEDLINE(R) ALL
Physical Therapy. 71(9):666-75; discussion 675-8, 1991 Sep.

[Clinical Trial. Journal Article. Randomized Controlled Trial]

UI: 1881957

The purpose of this study was to determine the effects of ultrasound and phonophoresis using an anti-inflammatory-analgesic cream (trolamine salicylate) on delayed-onset muscle soreness (DOMS). Repeated eccentric contractions were used to induce DOMS in the elbow flexors of 40 college-aged women. Subjects were then assigned randomly to one of four groups: (1) group 1 (n = 10) received sham ultrasound using placebo cream, (2) group 2 (n = 10) received sham ultrasound using trolamine salicylate cream, (3) group 3 (n = 10) received ultrasound using placebo cream, and (4) group 4 (n = 10) received ultrasound using trolamine salicylate cream. Subjects were treated on 3 consecutive days. Muscle soreness and active elbow range of motion were assessed daily prior to each treatment. The subjects in group 3 experienced an increase in DOMS, whereas no increase in soreness was observed in the subjects in group 4. The authors concluded that ultrasound enhanced the development of DOMS but that this enhancement was offset by the anti-inflammatory-analgesic action of salicylate phonophoresis. These findings suggest that salicylate phonophoresis may be useful in clinical situations in which it is desirable to administer ultrasound without increasing inflammation.

Version ID: 1

Status: MEDLINE

Authors Full Name: Ciccone, C D, Leggin, B G, Callamaro, J J

Institution: Ciccone, C D. Department of Physical Therapy, School of Health Sciences and Human Performance, Ithaca College, NY 14850.

Year of Publication: 1991

Link to the Ovid Full Text or citation:
Click here for full text options

137.

Assessment of triethanolamine salicylate release from the dermatological bases and the commercial products.

Babar A, Chickhale PJ, Plakogiannis FM

Ovid MEDLINE(R) ALL
Pharmaceutica Acta Helvetiae. 66(12):322-8, 1991.

[Journal Article]

UI: 1784579

Recently, triethanolamine salicylate (TEAS) is frequently being incorporated in several over-the-counter topical analgesic pharmaceutical products. Since the clinical efficacy of such dosage form depends upon the release of the active ingredient at the site of application, the present study was undertaken to study the in vitro release of the (TEAS) from commonly used ointment bases and two most popular commercial products in the U.S. market. Also, the effects of various penetration enhancers, such as, ethanol, propylene glycol, polyethylene glycol-400, dimethyl-sulfoxide (DMSO), polysorbate-80 and urea were evaluated. In general, the drug release from the experimental formulations was higher than the commercial products studied. The inclusion of the penetration enhancing ingredients increased the drug release from some of the formulations evaluated. The hydrophilic emulsion base with 10% ethanol exhibited the best in vitro drug release. The apparent viscosity profiles of the formulations showed no definite relationship with the amounts of drug release. However,

significant differences in the (TEAS) release from the experimental formulations were observed.

Version ID: 1

Status: MEDLINE

Authors Full Name: Babar, A, Chickhale, P J, Plakogiannis, F M

Institution: Babar, A. Division of Pharmaceutics and Industrial Pharmacy, Arnold & Marie Schwartz College of Pharmacy and Health Sciences, Long Island University, Brooklyn, New York.

Year of Publication: 1991

Link to the Ovid Full Text or citation:
Click here for full text options

138.

INFRARED ABSORPTION RATIO METHOD FOR DETERMINATION OF TRIETHANOLAMINE SALICYLATE IN OINTMENT.

HEISEY HO

Ovid MEDLINE(R) ALL
Journal of Pharmaceutical Sciences. 53:1553-4, 1964 Dec.

[Journal Article]

UI: 14255150

Version ID: 1

Status: MEDLINE

Authors Full Name: HEISEY, H O

Year of Publication: 1964

Link to the Ovid Full Text or citation:
Click here for full text options

From: s22
To: s22
Cc: s22
Subject: RE: Review of trolamine salicylate [SEC=OFFICIAL]
Date: Wednesday, 31 July 2024 12:47:56 PM
Attachments: image001.png
image002.png

Hi s22

Following discussions at leadership meeting, s22 is supportive of the implementation of the "Fail validation" rule in ELF. Can you use the same format as you did for *Caulophyllum thalictroides*? Thanks. s22 is aware this is coming their way.

We will most probably take this to ComTech in October to discuss with members and propose its removal following this meeting.

s22

From: s22
Sent: Tuesday, July 30, 2024 3:09 PM
To: s22 @Health.gov.au>
Cc: s22 @health.gov.au>
Subject: RE: Review of trolamine salicylate [SEC=OFFICIAL]

Thanks s22

Very comprehensive. The summary below shows we have very little information about the safety of trolamine salicylate currently, apart from the one sentence referenced from the US FDA GRAS Questions and Answers: FDA posts deemed final order and proposed order for over-the-counter sunscreen.

In comparison with PABA, the information we have on hand is very weak before we can remove from the Determination.

Can we discuss capacity to take on the lit review from our end? If there is an SCCS, or CIR report that has done a safety assessment of the ingredient, I think it's possible that CMES consider that information. If not, I can negotiate with s22 and see if Tox can take on that review as part of the sunscreen active review.

s22

From: s22 @Health.gov.au>
Sent: Tuesday, July 30, 2024 10:52 AM
To: s22 @health.gov.au>
Cc: s22 @health.gov.au>
Subject: RE: Review of trolamine salicylate [SEC=OFFICIAL]

Hi s22

Trolamine salicylate:

- As of 30 July 2024, there are zero listed medicines on the ARTG that contain trolamine salicylate.
- Trolamine is not included in the Cosmetic Products Regulation, Annex II – Prohibited Substances, whereas aminobenzoic acid (PABA) was.
- I have search TRIM and I haven't found any documents related to CMES and a review of trolamine salicylate. Majority of the documents that I found relate to OTC evaluations/enquiries.
- I also checked with s22 , and this ingredient was left for the sunscreen active review.
- Historically:
    - April 2016, name change from "triethanolamine salicylate" to "trolamine salicylate" (R16/266236).
    - December 2017, updates to the requirements to align with warning statements that apply to primary sunscreens.
    - November 2019, removal of transition period text.
    - March 2020, minor update to the requirements.

Aminobenzoic acid (PABA):

- November 2022, removed from the Determination (DO: D22-5507070).
- Based on the DO, it appears that no consultation was required and at that time there were zero listed medicines containing aminobenzoic acid.
- As an interim measure, a "Fail validation" rule was implemented – like what we have done for *Caulophyllum thalictroides*.
- The information relied upon to make the decision included:
    - 2006 – the Scientific Committee on Consumer Products (SCCP) concluded that there was insufficient data to perform a risk assessment of aminobenzoic acid.
    - 2013 – removed from Annex VI to Regulation (EC) No 1223/2009 and included in Annex II to Regulation (EC) No 1223/2009.
    - TGA safety review from 2010 (R10/28068) and 2020 (D20-689607).

Thanks

s22

From: s22 @health.gov.au>
Sent: Wednesday, July 24, 2024 5:45 PM
To: s22 @Health.gov.au>
Cc: s22 @health.gov.au>
Subject: Review of trolamine salicylate [SEC=OFFICIAL]

Hi s22

The sunscreen taskforce has referred the above-mentioned ingredient for our action.

Trolamine salicylate was identifies as a Category II: Not GRASE for use in sunscreens because of safety concerns by the US FDA. See Questions and Answers: FDA posts deemed final order and proposed order for over-the-counter sunscreen.

FDA's evaluation of the available safety data for trolamine salicylate, however (not used in marketed sunscreens any longer), has caused them to tentatively conclude that the risks associated with use of the active ingredient in sunscreen products outweigh its benefits. These risks include the potential for serious bleeding and salicylate toxicity (vomiting, hyperventilation, metabolic disturbances, coma and death) when this ingredient is used in sunscreens.

Can you please investigate if trolamine salicylate is included in any listed medicines?

- If no, then see what was the process we did for PABA prior to its removal from 26BB – what other information did we consider? I believe s22 did undertake an initial investigation, but I could be wrong. It could be a simple notification at ComTech that TGA will be proceeding to removing it from 26BB.

- If yes, we will get in touch with Tox to conduct a safety review of the ingredient before taking further regulatory actions.

No rush, can be done after LNR has gone out.

Thanks,
s22

s22
Director (A/g) – Complementary Medicines Evaluation Section
Complementary and OTC Medicines Branch
Medicines Regulation Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
T: s22 | E: s22 @health.gov.au
Location: Fairbairn, Gulgana Level 1 South East
PO Box 100, Woden ACT 2606, Australia
Gulgana First Aid Officer: On-site Tuesdays and Thursdays

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

OLD NAME	NEW NAME	STAGE	26BB Purpose	26BB	OLD Name specific requirements	NEW Names specific requirements	NEW Specific Requirements	ER Comment	SDR Comment	AR Action
s22	[redacted]									

s22

s22

S22

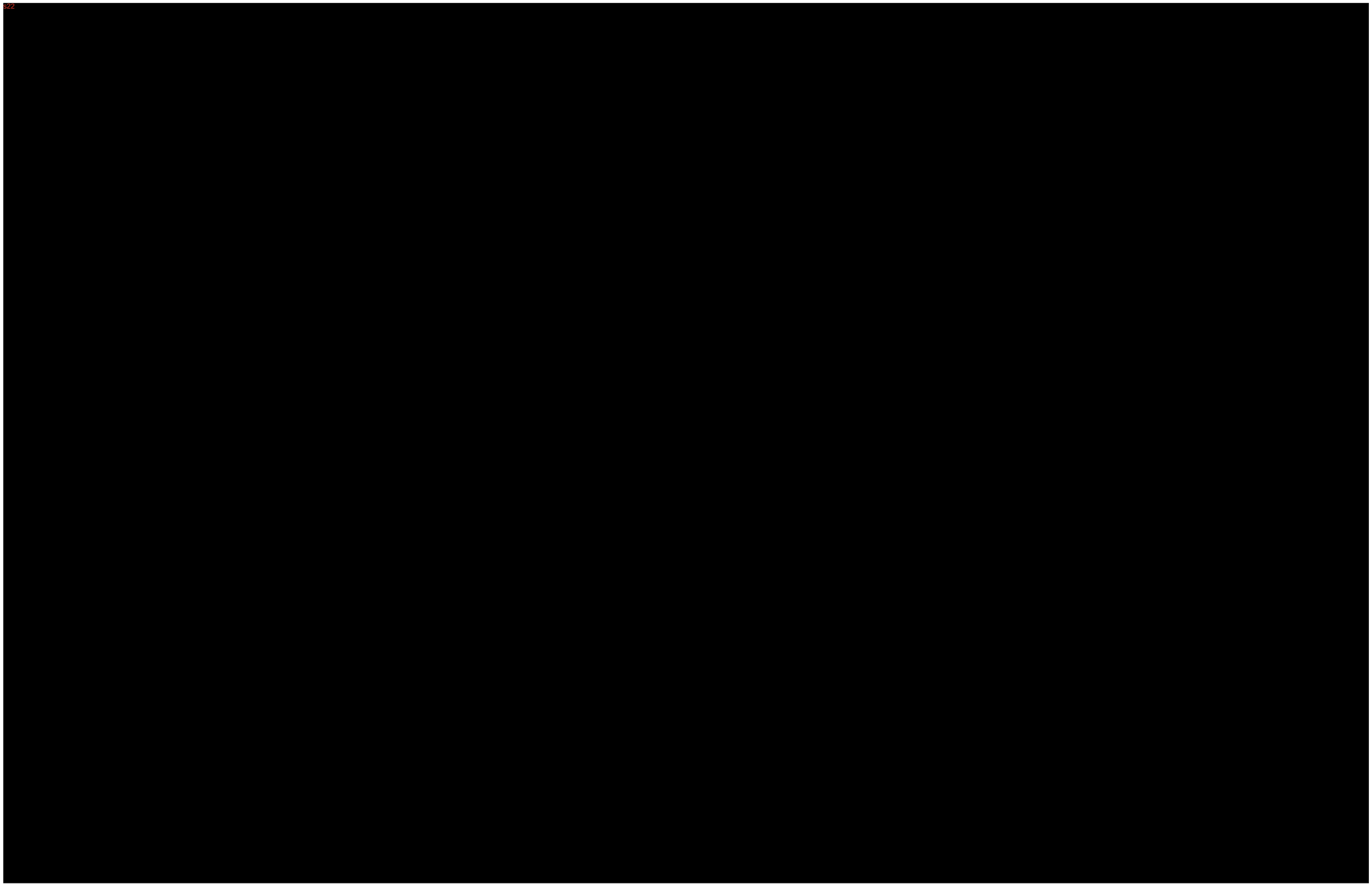
s22

[redacted]

Triethanolamine	trolamine	2a	E	OLD	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.	NOT IN 26BB	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.		Update topical use only group.	Complete. No change to wording. Left msg. s22 12/4/2016

OLD NAME	NEW NAME	STAGE	26BB USE	26BB	OLD Name specific requirements	NEW Names specific requirements	NEW Specific Requirements	SDR Comment	AR Action	
s22										

522


S22


522

s22

s22


S22

522

[redacted]

s22

s22


S22

s22


522

s22 [redacted]

Triethanolamine salicylate	trolamine salicylate	3a	A	OLD	Only for use as an active ingredient in sunscreens. Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 12%.	NOT IN 26BB	Only for use as an active ingredient in sunscreens. Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 12%.	OK	Complete. Left msg s22 14/04/2016

s22 [redacted]

From: s22
To:
Subject: FW: Review of trolamine salicylate [SEC=OFFICIAL]
Date: Tuesday, 6 August 2024 6:11:17 PM
Attachments: image003.png
image004.png
image005.png

Hi s22

There appears to be a listed medicine (export only) **DOUBLE D ARTHRITIS RUB trolamine salicylate 100mg/g cream tube** on the ARTG that is not a sunscreen.

We may need to consider if a listed medicine (export only) is considered a listed medicine, and whether removing trolamine salicylate will implicate its availability.

Let's chat more when you have had a chance to investigate if listed medicines for export only are listed under s 26A of the Act and if there are any exemptions for export only medicines.

s22

From: s22 @health.gov.au>
Sent: Tuesday, August 6, 2024 5:33 PM
To: s22 @health.gov.au>
Cc: s22 @health.gov.au>
Subject: RE: Review of trolamine salicylate [SEC=OFFICIAL]

Hi s22

The ingredient trolamine salicylate is currently included as an active ingredient in the following **registered OTC medicines** currently on the ARTG

Product name (AUST R)	Sponsor	ARTG indications
DENCORUB ARTHRITIS CREAM trolamine salicylate 100mg/g cream tube (AUST R 10148)	Church and Dwight Australia Pty Ltd	Provides temporary penetrating aspirin-like relief from pain associated with arthritis, rheumatism lumbago and fibrositis, as well as sore backs and muscles.
GOANNA ARTHRITIS CREAM trolamine salicylate 100mg/g tube (reformulation) (AUST R 78992)	Lupin Australia Pty Ltd	Provides temporary relief from pain associated with arthritis and rheumatism as well as back and muscle pain

The above-mentioned OTC products are not sunscreens. As such, I presume that the US FDA proposal that trolamine salicylate is *'Not GRASE for use in sunscreens because of safety concerns'*, would not directly apply to the above products.
I will need to look into whether FDA allows trolamine salicylate in other non-sunscreen OTC monograph products.

Note for information: Trolamine salicylate is also included as an active ingredient in DOUBLE D ARTHRITIS RUB trolamine salicylate 100mg/g cream tube which is a **Listed Medicine (Export Only).**

Thanks
s22

From: s22 @health.gov.au>
Sent: Monday, August 5, 2024 5:16 PM
To: s22 @health.gov.au>
Subject: FW: Review of trolamine salicylate [SEC=OFFICIAL]

Hi s22

I mentioned at leadership meeting last week about the ingredient trolamine salicylate and our intentions of removing it from the Permissible Ingredients Determination.

As of 30 July 2024, there are zero listed medicines on the ARTG that contain trolamine salicylate. As a risk mitigation step, we have now added a 'Fail validation' rule should any sponsor list a new medicine containing the ingredient.

CMES had not undertaken a de novo safety evaluation of trolamine salicylate (previously triethanolamine salicylate), however we note that majority of the documents in relation to the ingredient was associated with OTC evaluations.

Our intention is to bring the matter to ComTech for discussion if there are sponsors who are still utilising the ingredient, if not we would be inclined to remove it from the Determination due to safety reasons.

We wanted to check with OTCMES if there are any implications if we proceed with the option to bring the matter to ComTech.

Happy to discuss this when we are in office. I'll be in tomorrow, but have interviews. Can catch up in between .

Kind regards,
s22

From: s22 @Health.gov.au>
Sent: Tuesday, July 30, 2024 10:52 AM
To: s22 @health.gov.au>
Cc: s22 @health.gov.au>
Subject: RE: Review of trolamine salicylate [SEC=OFFICIAL]

Hi s22

Trolamine salicylate:

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- Trolamine is not included in the Cosmetic Products Regulation, Annex II – Prohibited Substances, whereas aminobenzoic acid (PABA) was.

- I have search TRIM and I haven't found any documents related to CMES and a review of trolamine salicylate. Majority of the documents that I found relate to OTC evaluations/enquiries.
- I also checked with s22 and this ingredient was left for the sunscreen active review.
- Historically:
  - April 2016, name change from "triethanolamine salicylate" to "trolamine salicylate" (R16/266236).
  - December 2017, updates to the requirements to align with warning statements that apply to primary sunscreens.
  - November 2019, removal of transition period text.
  - March 2020, minor update to the requirements.

Aminobenzoic acid (PABA):

- November 2022, removed from the Determination (DO: D22-5507070).
- Based on the DO, it appears that no consultation was required and at that time there were zero listed medicines containing aminobenzoic acid.
- As an interim measure, a "Fail validation" rule was implemented – like what we have done for *Caulophyllum thalictroides*.
- The information relied upon to make the decision included:
  - 2006 – the Scientific Committee on Consumer Products (SCCP) concluded that there was insufficient data to perform a risk assessment of aminobenzoic acid.
  - 2013 – removed from Annex VI to Regulation (EC) No 1223/2009 and included in Annex II to Regulation (EC) No 1223/2009.
  - TGA safety review from 2010 (R10/28068) and 2020 (D20-689607).

Thanks

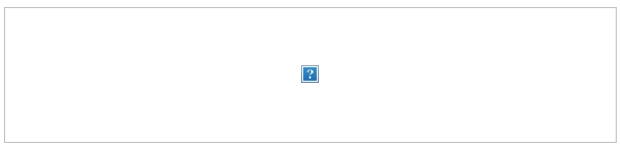
s22

From: s22 @health.gov.au>
Sent: Wednesday, July 24, 2024 5:45 PM
To: s22 @Health.gov.au>
Cc: s22 @health.gov.au>
Subject: Review of trolamine salicylate [SEC=OFFICIAL]

Hi s22

The sunscreen taskforce has referred the above-mentioned ingredient for our action.

Trolamine salicylate was identifies as a Category II: Not GRASE for use in sunscreens because of safety concerns by the US FDA. See Questions and Answers: FDA posts deemed final order and proposed order for over-the-counter sunscreen.



FDA's evaluation of the available safety data for trolamine salicylate, however (not used in marketed sunscreens any longer), has caused them to tentatively conclude that the risks associated with use of the active ingredient in sunscreen products outweigh its benefits. These risks include the potential for serious bleeding and salicylate toxicity (vomiting, hyperventilation, metabolic disturbances, coma and death) when this ingredient is used in sunscreens.

Can you please investigate if trolamine salicylate is included in any listed medicines?

- If no, then see what was the process we did for PABA prior to its removal from 26BB – what other information did we consider? I believe s22 did undertake an initial investigation, but I could be wrong. It could be a simple notification at ComTech that TGA will be proceeding to removing it from 26BB.

- If yes, we will get in touch with Tox to conduct a safety review of the ingredient before taking further regulatory actions.

No rush, can be done after LNR has gone out.

Thanks,

s22

s22
Director (A/g) – Complementary Medicines Evaluation Section
Complementary and OTC Medicines Branch
Medicines Regulation Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
T: s22 | E: s22 @ ov.au
Location: Fairbairn, Gulgana Level 1 South East
PO Box 100, Woden ACT 2606, Australia

Gulgana First Aid Officer: On-site Tuesdays and Thursdays

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22
To: s22
Subject: FW: Request for literature search: Trolamine salicylate [SEC=OFFICIAL]
Date: Thursday, 22 August 2024 11:54:51 AM
Attachments: image001.png
image002.png
image003.gif
image004.png
Sunscreen Trolamine salicylate.doc

Hi s22

I requested a literature search from the Library (please see attached).

I couldn't find any specific information relating to risks associated with trolamine salicylate.

Thanks

s22

From: IRRS <IRRS@health.gov.au>
Sent: Friday, August 16, 2024 9:27 AM
To: s22 @Health.gov.au>
Subject: RE: Request for literature search: Trolamine salicylate [SEC=OFFICIAL]

Hi s22

Sorry for the delay, the database didn't want to send your results for some reason.
I had to export them in a different format.
138 possibly relevant articles are attached.

Regards
s22
Senior Librarian – Information Resources and Research Services (IRRS)
Committees and Research Services Section
Regulatory Engagement Branch

Regulatory Practice and Support Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
T: s22 | E: s22 @health.gov.au
Location: Scherger Drive, Fairbairn
PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 @Health.gov.au>
Sent: Thursday, August 8, 2024 12:43 PM
To: IRRS <IRRS@health.gov.au>

Subject: Request for literature search: Trolamine salicylate [SEC=OFFICIAL]

Good afternoon

Can you please help me by conducting a literature search in relation to the below?

- Ingredient name: Trolamine salicylate
- Keywords: “sunscreen”, “dermal carcinogenicity”, “systemic carcinogenicity”, “developmental and reproductive toxicity”, “toxicokinetics”, “endocrine effects”, “safety”, “chronic exposure”, “dermal irritation”, “dermal sensitisation”, and “phototoxicity”.

Please let me know if you require any further details.

Thanks

s22 [redacted]

From: s22
To: s22
Subject: RE: TRIM: Re: Maximum Concentration Permitted of Homosalate CCEMS:03980000179 [SEC=OFFICIAL]
Date: Thursday, 22 August 2024 1:29:24 PM
Attachments: Sunscreen Trolamine salicylate.doc
image001.png
image002.png
image003.png
image004.png
image005.png
image006.png
image007.jpg

Thanks s22

To assist your team in undertaking the safety review of trolamine salicylate, s22 has kindly requested the Library perform a literature search with relevant search terms for the ingredient (see attached lit search output).

We hope this helps in the review.

Kind regards,
s22

From: s22 @health.gov.au>
Sent: Friday, August 16, 2024 8:46 AM
To: s22 @health.gov.au>; s22 @health.gov.au>
Subject: RE: TRIM: Re: Maximum Concentration Permitted of Homosalate CCEMS:03980000179 [SEC=OFFICIAL]

Hi s22

A review of 4-MCS and trolamine salicylate can be done but I will discuss further with the Sunscreens Taskforce about timing and priorities.

With thanks
s22

From: s22 @health.gov.au>
Sent: Thursday, August 15, 2024 4:08 PM
To: s22 @health.gov.au>; s22 @health.gov.au>
Subject: RE: TRIM: Re: Maximum Concentration Permitted of Homosalate CCEMS:03980000179 [SEC=OFFICIAL]

Hi s22

We have received a few follow up emails from Veganic SKN about homosalate and 4-MBC, specifically mentioning that 4-MBC has recently been included in the European Commission's Annex II: list of substances prohibited in cosmetic products, and therefore be removed from the EU cosmetics market.

In his most recent email, Joseph has also mentioned that trolamine salicylate is classified not

GRASE by the US FDA. I have included a statement about the risk mitigation steps we have taken so far. It is currently in 1 listed medicine (export only).

We are seeking legal advice on a separate complaint letter that Veganic has written to us in relation to homosalate and other UV filters currently used in listed medicines. I understand homosalate is included in the current Early Draft TGA Safety Review on Sunscreen Ingredients that has been circulated to Accord and CHPA recently, s22 given the persistent enquiries and complaints that the TGA is receiving, could we also prioritise the safety review of 4-MBC and trolamine salicylate when your team gets a chance?

CMES have drafted the following response to Joseph, I'd appreciate if you both can review so we can send this back to Joseph.

Thanks,
s22

Dear Joseph,

Thank you for your inquiry.

The TGA does not release evaluation reports, however you can search for publicly available National Industrial Chemicals Notification and Assessment Scheme reports here.

The TGA's regulatory decisions are based on a comprehensive analysis of scientific evidence, tailored to Australia's specific conditions and legal framework. We consider a wide range of data, including that which may not be used by other international regulatory bodies such as animal testing data which is banned for sunscreen ingredients in the EU. As previously advised, we are conducting a thorough literature review of sunscreen active ingredients and considering all available scientific information.

Please note the Australian sunscreen exposure model has recently closed on 13 August and is not yet finalised. We will consider all stakeholder feedback before finalising the model in 2024, which will be utilised to finalise our safety assessments.

Regarding trolamine salicylate in listed therapeutic sunscreens, the TGA took proactive measures to prevent listing of new medicines containing trolamine salicylate in the Australian Register of Therapeutic Goods (ARTG) until an updated safety review could be conducted. At the time these measures were taken, there were no listed medicines that contained trolamine salicylate in the Australian market.

We do not have further updates we can provide you as we are in the midst of the consultation process. We encourage you to monitor the TGA website for any developments or changes in regulations which will be publicly communicated.

Kind regards,

From: CMES <CMES@health.gov.au>

Sent: Thursday, August 15, 2024 2:05 PM
To: [redacted]@health.gov.au>; [redacted]@health.gov.au>
Subject: FW: TRIM: Re: Maximum Concentration Permitted of Homosalate CCEMS:03980000179 [SEC=OFFICIAL]

Hi [redacted]

Please kindly find the following follow up email from Joseph,

Kind regards,

[redacted]

From: Complementary Medicines <complementary.medicines@health.gov.au>
Sent: Thursday, August 15, 2024 1:51 PM
To: CMES <CMES@health.gov.au>
Subject: FW: TRIM: Re: Maximum Concentration Permitted of Homosalate CCEMS:03980000179 [SEC=OFFICIAL]

Hi CMES,

Please see below follow up email from Joseph in response to the holding email sent earlier today

Thanks, [redacted]

From: Joseph Mizikovsky <ceo@veganicskn.com>
Sent: Thursday, August 15, 2024 12:58 PM
To: Complementary Medicines <complementary.medicines@health.gov.au>
Subject: Re: TRIM: Re: Maximum Concentration Permitted of Homosalate CCEMS:03980000179 [SEC=OFFICIAL]

Dear Complementary and OTC Medicines Branch,

Thank you for the update, would it be possible to speak to someone or get an official position on if the TGA is opposed to changes being made to the current list of approved UV filters?

I am preparing an official request for Mark Butler, with the aim of seeking a Judicial Review of the decisions to keep approving these chemical UV filters. It would be great to have your support and this way you would not have to deal with justifying why they were given to him to sign off on in June of this year.

For example Trolamine Salicylate is approved for use in sunscreen at 12% in the permissible ingredients list.

FDA Not GRASE Official Statement: “In the case of trolamine salicylate, these **risks include the potential for serious bleeding and salicylate toxicity (vomiting, hyperventilation,**

metabolic disturbances, coma and death) when this ingredient is used in sunscreens.”[1]

---

[1] Questions and Answers: FDA posts deemed final order and proposed order for over-the-counter sunscreen | FDA

Thank you,

Joseph Mizikovsky

Head of Strategic Partnerships | VeganicSKN Ltd. | BBus(Marketing)

www.veganicskn.com

243 Milton Road, Milton QLD 4064, Australia

From: Complementary Medicines <complementary.medicines@health.gov.au>
Sent: Thursday, 15 August 2024 11:47 AM
To: Joseph Mizikovsky <ceo@veganicskn.com>
Subject: RE: TRIM: Re: Maximum Concentration Permitted of Homosalate CCEMS:03980000179 [SEC=OFFICIAL]

Dear Joseph,

Thank you for your email to the Therapeutic Goods Administration (TGA) on August 2, 2024.

Please note that your enquiry is being addressed by the Complementary and OTC Medicines Branch. We seek to provide you with a response as soon as possible.

We appreciate your patience on this matter.

Regards

Complementary Medicines
Complementary and OTC Medicines Branch
Phone: 02 6289 4627
Email: complementary.medicines@health.gov.au

Therapeutic Goods Administration

Department of Health and Aged Care
PO Box 100
Woden ACT 2606
www.tga.gov.au

For information regarding compliance activities for listed medicines, please subscribe to the TGA Newsletters at https://www.tga.gov.au/subscribe-updates

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This information is given to you without prejudice and is not binding on the TGA. It is the responsibility of the sponsor to ensure that all of the legislative requirements are met.

From: Joseph Mizikovsky <ceo@veganicskn.com>
Sent: Friday, August 2, 2024 3:30 PM
To: Complementary Medicines <complementary.medicines@health.gov.au>
Subject: TRIM: Re: Maximum Concentration Permitted of Homosalate CCEMS:03980000179 [SEC=OFFICIAL]

Dear Complementary and OTC Medicines Branch,

I hope this email finds you well. I wanted to bring to your attention that the EU has recently deemed 4-MBC unsafe for use at any concentration. This underscores the urgency of my request.

I am seeking the original approval documents for 4-MBC and Homosalate, specifically the NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME Public Report or the TGA report produced during their initial market approval. My focus is on the points regarding endocrine-disrupting abilities and systemic absorption, as recent data suggest these ingredients no longer meet the criteria for approval under current standards.

Given that the data originally used to approve these UV filters is now considered invalid, it stands to reason that the approval of these ingredients should have been revoked. Can you assist me in obtaining these documents or direct me to the appropriate department for this

request?

I am compiling this information for an upcoming publication that aims to highlight the discrepancies between the data used for the approval of certain chemical UV filters in Australia and the globally recognized safety gaps associated with their use. This includes the new proposed Australian Sunscreen Exposure model, which indicates that the dosage amounts used for their approval may be significantly understated.

It is crucial for us to ensure public health safety by aligning with international standards and recent scientific findings. I believe a prompt response will be beneficial in addressing these concerns effectively.

Thank you for your assistance.

Best regards,

Joseph Mizikovsky

Head of Strategic Partnerships | VeganicSKN Ltd. | BBus(Marketing)

www.veganicskn.com

243 Milton Road, Milton QLD 4064, Australia

From: Complementary Medicines <complementary.medicines@health.gov.au>
Sent: Friday, 3 May 2024 3:49 PM
To: Joseph Mizikovsky <ceo@veganicskn.com>
Subject: FW: Maximum Concentration Permitted of Homosalate CCEMS:03980000179 [SEC=OFFICIAL]

Dear Joseph,

Thank you for reaching out with your concerns regarding the use of Homosalate in sunscreens. We understand the importance of ensuring the safety and efficacy of ingredients used in sunscreens to protect Australians from the harmful effects of the sun. I note that the TGA has corresponded with your company on sunscreen ingredients in previous emails.

As advised previously, the TGA is actively reviewing the safety of active ingredients in sunscreens, including Homosalate, in light of recent international scientific reviews and regulatory actions. This is a thorough scientific review and includes a comprehensive literature search and assessment to ascertain the potential risks associated with these ingredients. The TGA is committed to taking appropriate regulatory action based on the findings of this review and will publish the outcomes on the TGA website once completed.

While this review is in progress, and as you have rightly pointed out, it is the legal responsibility of each sponsor to ensure the safety of their products, including manufacturing processes, presentation, and ongoing pharmacovigilance responsibilities.

We acknowledge that regulatory standards vary internationally, with some jurisdictions (such as the European Union) classifying sunscreens as cosmetics rather than therapeutic goods. The TGA conducts its own assessments to ensure that ingredients are suitable for use in therapeutic sunscreens in Australia, reflecting our unique environment and sun exposure levels.

We appreciate your proactive approach to public health and safety. Rest assured, the TGA takes these matters seriously and is working diligently to ensure that all sunscreen products available in Australia meet the highest safety standards.

We trust this information is of assistance.

Regards

Complementary Medicines
Complementary and OTC Medicines Branch
Phone: 02 6289 4627
Email: complementary.medicines@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100
Woden ACT 2606
www.tga.gov.au

Stay in touch by following us on 

This information is given to you without prejudice and is not binding on the TGA. It is the responsibility of the sponsor to ensure that all of the legislative requirements are met.

---------- Original Message ----------
From: Joseph Mizikovsky <ceo@veganicskn.com>;
Received: Wed Mar 06 2024 16:20:20 GMT+1100 (Australian Eastern Daylight Time)
To: TGA Info <info@tga.gov.au>; info-Queue <info@tga.gov.au>;
Cc: s22 [redacted]
Subject: Maximum Concentration Permitted of Homosalate

Dear Therapeutic Goods Administration,

I am writing to express my serious concerns regarding the current regulatory stance on the use of Homosalate in sunscreen products in Australia, specifically those with concentrations up to 10%. Recent international developments and scientific assessments have raised significant concerns regarding the safety of Homosalate, particularly its endocrine-disrupting properties.

The United Kingdom, following a comprehensive review, has already imposed restrictions on the use of Homosalate, limiting its concentration to 7.34% and confining its application to face products only. This action was taken more than a year ago in response to the findings of the Scientific Committee on Consumer Safety (SCCS) which concluded that Homosalate is not safe as a UV-filter in cosmetic products at

concentrations above 0.5% due to potential health risks.

The SCCS's assessment, issued on June 24-25, 2021, and the subsequent advice on December 2, 2021, clearly indicates that Homosalate poses a risk to human health when used in concentrations currently allowed by the TGA. It is concerning that products containing up to 6% Homosalate, such as the Cancer Council Everyday sunscreen, are widely used across Australia, including on children, without adequate warnings about their potential health risks.

Given the availability of safer alternatives on the market, I believe it is unnecessary and potentially harmful to continue allowing the use of Homosalate in concentrations exceeding 0.5% in products intended for application beyond the face - and the EU and UK agrees. I urge the TGA to take immediate action to re-evaluate the safety and regulations surrounding Homosalate in sunscreen products. Specifically, I request a recall of all products containing more than 0.5% Homosalate that are not exclusively targeted for facial use.

The health and safety of Australian consumers should be of paramount concern, and regulatory standards must reflect the latest scientific evidence to ensure that all available products are safe for use. I plan to make this information public next month and would greatly appreciate a timely response, providing sufficient justification for the continued use of Homosalate at current concentrations, should there be any.

I understand it is the sponsors responsibility to ensure their product is safe, and encourage Cancer Council to make public the safety data they should already have on hand.

Thank you for your attention to this urgent matter. I look forward to your prompt response.

Please see below exert from the British Government:

(9) In light of concerns related to potential endocrine disrupting properties of Homosalate, the Commission launched a public call for data in 2019. The industry submitted scientific evidence to demonstrate the safety of Homosalate when used in cosmetic products. The Commission requested the SCCS to carry out a safety assessment of Homosalate in view of the information provided.

(10) The SCCS concluded in its opinion of 24-25 June 2021 (4) that Homosalate is not safe when used as a UV-filter in cosmetic products at concentrations of up to 10 %. The SCCS found that the use of Homosalate as a UV filter in cosmetic products is safe for the consumer only up to a maximum concentration of 0,5 % in the final product.

(11) On 30 July 2021, to ensure broad availability of UV-filters and consequently adequate sun protection for consumers, industry submitted a re-calculation of the margin of safety based only on the use of Homosalate in face products (face cream and pump-spray products). On the basis of the information provided by industry, and considering the

concerns related to potential endocrine disrupting properties of Homosalate, the SCCS issued scientific advice on 2 December 2021 (5), where it concluded that Homosalate is safe as a UV-filter at concentrations up to 7,34 % when used in face products in the form of cream and pump spray. Therefore, the use of Homosalate should be restricted to face products (non-spray and pump spray products) only, up to a maximum concentration of 7,34 %. The combined use of Homosalate up to 0,5 % in all cosmetic products and up to 7,34 % in face products is not considered safe by the SCCS since the margin of safety of such combined use is below 100.

(12) In light of the SCCS scientific advice, it can be concluded that there is a potential risk to human health arising from the use of Homosalate as a UV filter in cosmetic products in the concentration currently allowed. Therefore, the use of Homosalate should be restricted to face products (non-spray and pump spray products) only up to a maximum concentration of 7,34 %.

Joseph Mizikovsky

Head of Strategic Partnerships | VeganicSKN Ltd. | BBus(Marketing)

www.veganicskn.com

243 Milton Road, Milton QLD 4064, Australia

MINUTE TO DEPUTY SECRETARY SKERRITT

To: Adj. Professor John Skerritt

Through: Nick Henderson
cc: Tracey Duffy

Note: The document is updated with issues 9 and 10. **Dated**: 16 August 2022.

SUBJECT Sunscreen related issues across TGA

Purpose

- To provide you the with an update on COMB sunscreen related activities and other current sunscreens issues from across the TGA.

COMB ongoing sunscreen activities

s22

[redacted]

s22

[redacted]

s22

s22

s22

[redacted]

s22

[redacted]

s22

[redacted]

s22

s22 [redacted]

Other current sunscreens issues from across the TGA

Issue 5: Sunscreen ingredients that are no longer on the US FDA's Generally Recognised as Safe and Effective (GRASE) list

- The FDA published two studies in 2019 and 2020 looking at the dermal absorption of the most common active ingredients in sunscreens (Matta et al., 2020; 2019). Both studies demonstrated that the studied sunscreen active ingredients were systemically absorbed in significant quantities above the FDA's safety threshold (0.5 ng/mL) for carcinogenicity risk.
- The FDA issued a proposed rule to update the sunscreen regulatory requirements stating that certain active ingredients were no longer GRASE. The FDA expects that sunscreen active ingredients that are absorbed into the bloodstream at 0.5 ng/mL or higher, or that have potential safety concerns, need to undergo further toxicological testing. As part of this rule the FDA sought safety data from industry on 12 active sunscreen ingredients.
- The FDA has not specified when the proposed rule will be finalised, however they have indicated they will defer issuing the final order on the GRASE status of certain ingredients if they have received satisfactory indication of timely and diligent progress on the necessary studies for a specific ingredient. This deferral would be for up to one year, with a possibility of extension depending on further satisfactory progress with the studies.
- In addition to the FDA's non-GRASE ingredients, in December 2021 the Scientific Committee on Consumer Safety (SCCS) published an opinion that is yet to be finalised for the ingredient 4-Methylbenzylidene camphor (4-MBC). The opinion indicates the maximum concentration of 4% in cosmetic ingredients does not appear to be safe due to endocrine disrupting potential. As of 6 May 2022, there are 206 listed sunscreen products on the ARTG using this ingredient.
- The FDA published a list of sunscreen ingredients that are, or are no longer, GRASE:
  - **GRASE** for sunscreens:
    - zinc oxide
    - titanium dioxide[3]
  - **Not GRASE**, due to evidence that demonstrates these ingredients are not safe for sunscreens:
    - aminobenzoic acid (PABA)
    - trolamine salicylate
      - As of 6 May 2022, these ingredients are not used in any of the currently listed sunscreens on the ARTG, however trolamine salicylate is used as an active ingredient in two OTC medicines (Dencorub arthritis cream AUST R 10148 and Goanna arthritis cream AUST R 78992 – from different sponsors).

[3] In 2016, the Toxicology Section published a scientific literature review regarding safety concerns surrounding zinc oxide (ZnO) and titanium dioxide (TiO2) nanoparticles (NPs) present in sunscreens. The two main issues considered in this review are the evidence for the ability of these NPs to penetrate the skin to reach viable cells and the potential toxicity exerted by them.

- **Not GRASE**, due to evidence of the ability of these ingredients to penetrate the skin and reach viable cells systemically, and the potential toxicity exerted by them. Additional data are needed to show that these ingredients are safe for sunscreens:
    - cinoxate
    - dioxybenzone
    - ensulizole
    - homosalate
    - meradimate
    - octinoxate
    - octisalate
    - octocrylene
    - padimate
    - sulisobenzone
    - oxybenzone
    - avobenzone

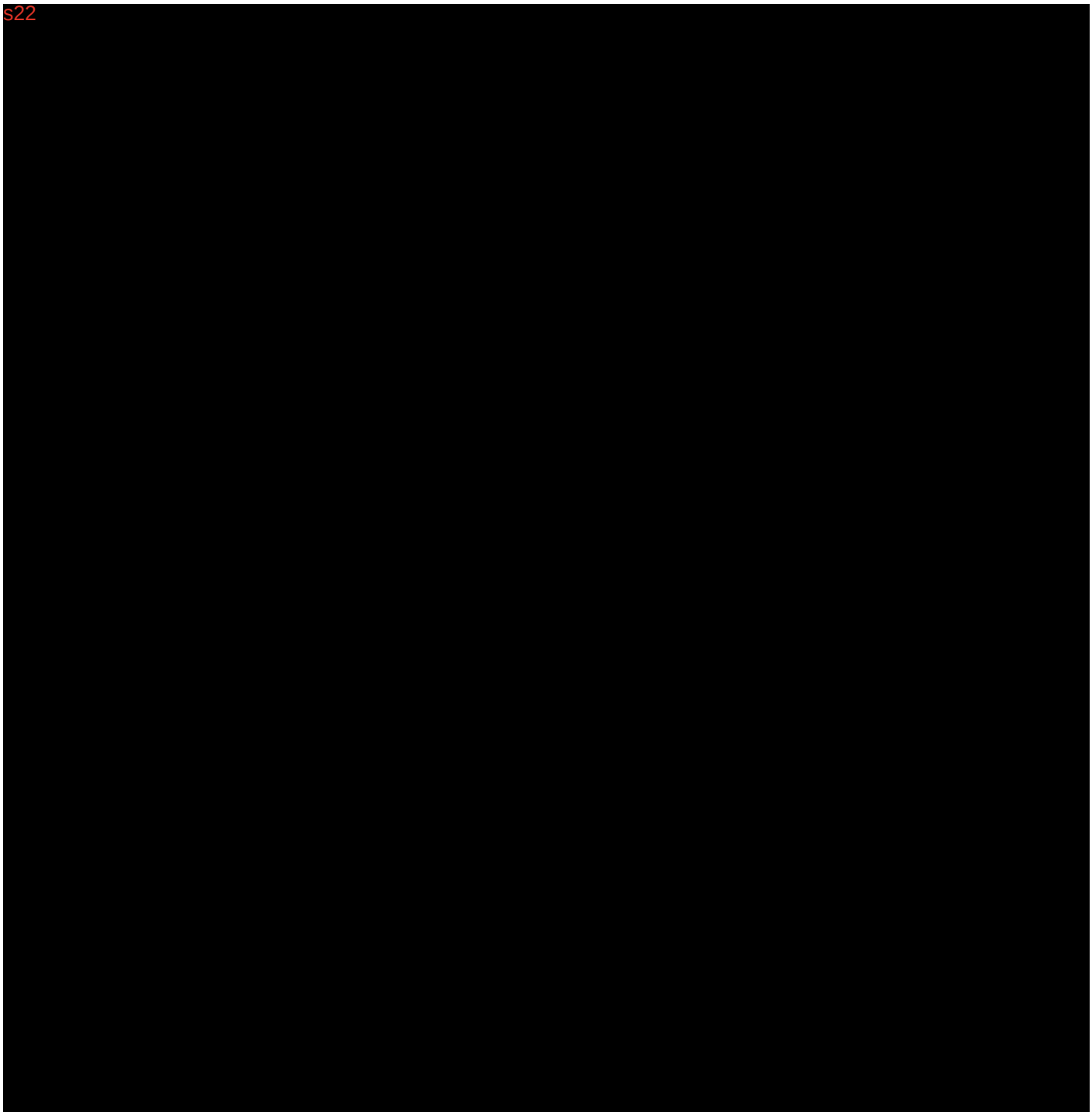
  Some of these ingredients have other purposes and are also likely to be used in cosmetics and other consumer goods in Australia e.g. octinoxate is used as a photostabiliser in make-up products, nail polish, hair spray etc.

Current position and work in progress

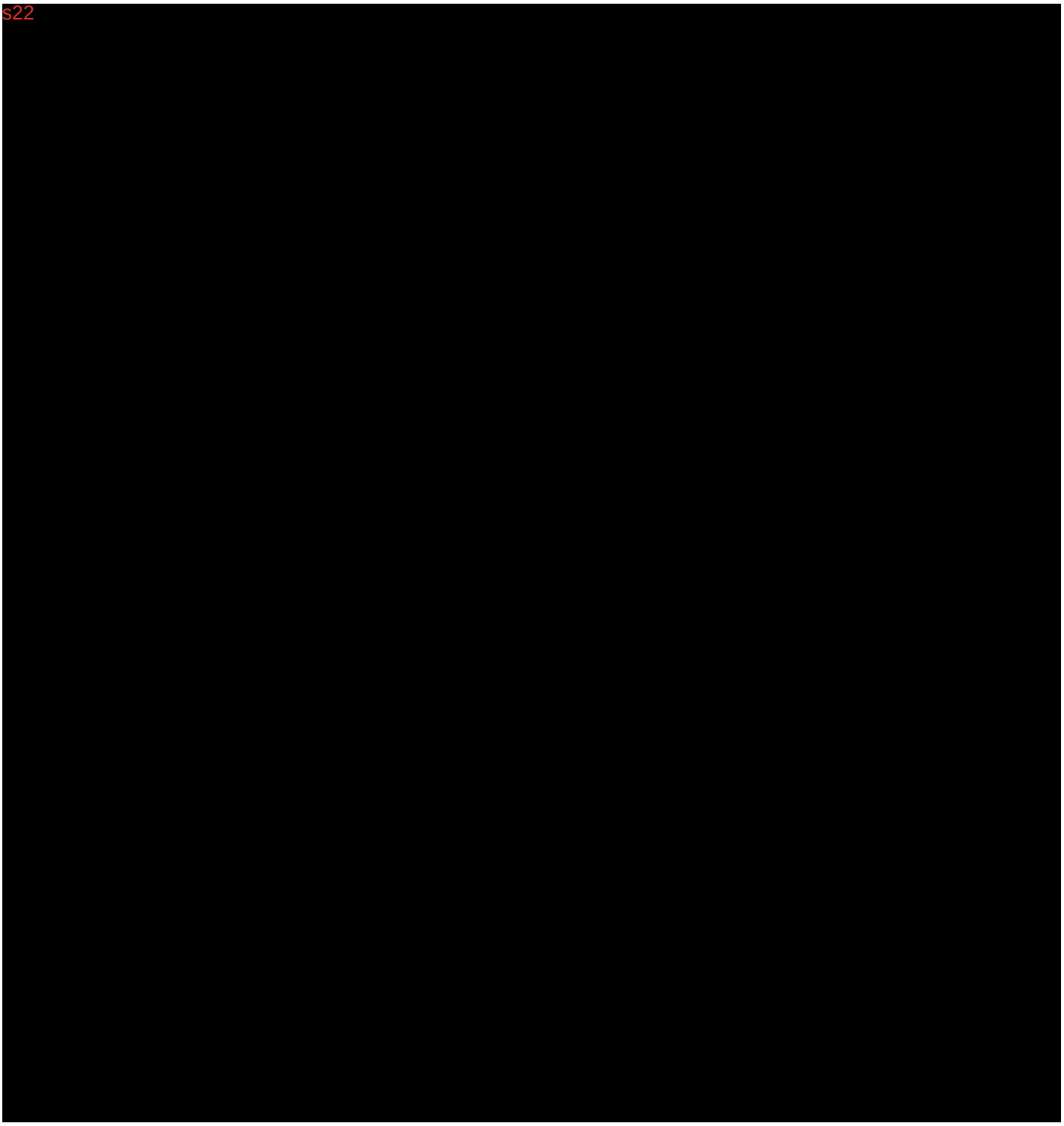
- At the last ComTech meeting held on 13 April 2022, COMB informed industry that TGA are undertaking a literature review of seven active ingredients identified by the FDA as no longer being GRASE. The ingredients (avobenzone, ethylhexyl triazone, homosalate, octocrylene, octinoxate, oxybenzone and phenylbenzimidazole sulfonic acid) were selected for priority review considering their reported use in sunscreen products marketed in Australia in addition to the safety signals reported in media and overseas.
- A draft literature review report has been prepared by the Toxicology section and comments from COMB are being considered by the Toxicology Section. It is proposed to provide a copy of the final report to colleagues at the US FDA who have been discussing with the Toxicology Section the toxicology and proposed regulatory actions of the FDA's work on sunscreen actives in the USA.
- 4-Methylbenzylidene camphor may be included in a separate toxicology review as this was not part of the initial FDA safety signal.
- COMB intends to remove PABA from the Determination at the next opportunity (ETA August/September) as this ingredient has been identified as not being safe, and is not used in any sunscreens currently in Australia. COMB is investigating whether to remove trolamine salicylate from the Determination as it is also not used in any listed medicines.
- There are two new sunscreen active ingredient applications that are under evaluation.
- Based on the result of investigation, potential future work could include:
    - Communicating the findings of the literature review to industry, Cancer Council Australia, Australian Industrial Chemicals Introduction Scheme (AICIS) and FDA.
    - A call for further safety data from industry and publishing the findings on the TGA website.

- Bringing the findings to the attention of the Advisory Committee on Chemicals Scheduling (ACCS) Delegate, who may seek ACCS advice. As these ingredients are also used in cosmetics and potentially other consumer goods, it may be necessary to amend the Poisons Standard to account for use in other consumer goods. It will be important to discuss these findings with AICIS prior to engaging with ACCS.
- Updating the Determination to remove or update the requirements for any ingredients that pose an unacceptable safety risk in listed medicines. This may be updated after consideration through the scheduling process.
- Clarifying future safety and quality pre-market evaluation requirements (see **Issue 1**) to address issues identified in the review, for example to focus on skin absorption.

s22



s22



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[redacted]

s22

Consultation

Input from COMB, SEB, MQB, PB, Labs

Contact officer: Cheryl McRae

Phone: 02 62893365

TRIM ref: **D22-5459772**

Please Discuss / Noted

Adj. Professor John Skerritt

/ 05 / 22

From: MCRAE, Cheryl
To: HENDERSON, Nick; VUCKOVIC, George; s22 [redacted]
Subject: FW: Sunscreen briefing [SEC=OFFICIAL]
Date: Wednesday, 5 October 2022 11:43:41 AM
Attachments: Sunscreen Active Ingredients safety.docx
image001.gif

FYI – came across this early brief indicating early days of the tox review of sunscreen ingredients on the back of FDA investigations

From: s22 [redacted]@health.gov.au>
Sent: Wednesday, 22 January 2020 1:55 PM
To: SKERRITT, John <John.Skerritt@health.gov.au>
Cc: MCRAE, Cheryl <Cheryl.McRae@health.gov.au>; s22 [redacted]@health.gov.au>; WISEMAN, Michael <Michael.Wiseman@health.gov.au>
Subject: FW: Sunscreen briefing [SEC=OFFICIAL]

Dear John

Please find attached the briefing paper that s22 [redacted] prepared (Sep 2019) in response to the FDA's research (Matta et al, JAMA 2019) in to the absorption of sunscreen active ingredients. We also provided input into the 'TGA topics' website article on sunscreens that included reference to the FDA study: https://www.tga.gov.au/blogs/tga-topics/everything-you-ever-wanted-know-about-sunscreens-were-afraid-ask

The Toxicology Section is currently undertaking an audit of the *toxicological data* that the TGA holds on the *active ingredients* used in sunscreens. This is in response to the FDA's call for more safety information on 12 sunscreen ingredients https://www.fda.gov/media/124654/download; https://www.federalregister.gov/documents/2019/02/26/2019-03019/sunscreen-drug-products-for-over-the-counter-human-use

Kind regards

s22 [redacted]
Director
Toxicology Section | Scientific Evaluation Branch | Medicines Regulation Division

Phone: s22 [redacted]
Email: s22 [redacted]@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

From: s22 [redacted]@health.gov.au>
Sent: Friday, 20 September 2019 11:30 AM
To: s22 [redacted]@health.gov.au>
Subject: Sunscreen briefing [SEC=OFFICIAL]

Hi s22 [redacted]

Here is the updated briefing paper.

Cheers,

s22 [redacted]
Senior Toxicologist
Toxicology Section | Scientific Evaluation Branch | Medicines Regulation Division

Phone: s22 [redacted]
Email: s22 [redacted] @health.gov.au
TGA: FG 61

Sunscreen Active Ingredients

Key issues

- Maintaining public confidence in the safety and effectiveness of sunscreens is an important part of the TGA's role in sunscreen regulation.
- Concerns about the safety of sunscreens expressed in the media and by consumer groups could lead to a loss of public confidence in this key component of Australia's skin cancer-prevention strategy.
- Recent concerns about the skin absorption of active ingredients in sunscreens have arisen in part by the FDA's proposed changes in the regulation of sunscreen ingredients (announced in Feb 2019).
- In Australia, sponsors wishing to use an active ingredient that is not on the Therapeutic Goods (Permissible Ingredients) Determination must submit data to establish the safety and efficacy of the ingredient under its proposed conditions of use. However, safety data for existing 'grandfathered' ingredients may be limited.
- Options for possible regulatory action include:
  - Assess of ingredients currently approved by TGA as actives in sunscreens (comparison with FDA's 'chemicals of concern'; approval history; evidence of safety assessments)
  - Set up literature alerts for new safety data on sunscreen ingredients
  - Set priorities for higher risk ingredients
  - Conduct targeted safety reviews
  - Forge closer links with FDA sunscreen regulators
  - Update website advice
  - Consult with external stakeholders.

Background

According to consumers, real or perceived risks[1] of sunscreen use include:

- Contact dermatitis
- Vitamin D deficiency
- Nanoparticles
- Hormonal effects

Sunscreen use is recommended whenever the UV index is ≥ 3 to all exposed parts of the body by people from ages 6 months and above.[2] Sunscreen should be applied liberally, with

[1] Whiteman, D.C. et al (2019) Aus & NZ Journal of Public Health 43 (2): 171-5

[2] https://www.cancer.org.au/preventing-cancer/sun-protection/about-sunscreen.html

The recommended application rates for sunscreen, as published on the TGA website,[3] are 30-40 mL per application (in adults). Thus the general population following official recommendations on sunscreens may potentially be exposed to significant amounts of sunscreen ingredients over their lifetime (sunscreen is recommended for infants from 6 months of age).

The Toxicology section was recently asked for input into a 'TGA topics' website article on sunscreens.[4] Under a heading 'Are sunscreens safe?' the article discussed the results of a recent study conducted by the FDA which showed that some sunscreen ingredients are absorbed into the blood stream.[5] This study was commissioned following changes to sunscreen regulation proposed by the FDA in February 2019.[6] This study generated considerable media attention.

FDA proposed sunscreen regulation changes

The FDA's proposed new rule for sunscreen active ingredients proposes that:

- Zinc oxide and titanium dioxide are GRASE[7] when used in sunscreens
- Para-aminobenzoic acid (PABA) and trolamine salicylate are proposed as not safe and effective for sunscreen use[8]
- More safety information (in particular, carcinogenicity and reproductive toxicity data) is needed for 12 sunscreen ingredients (cinoxate, dioxybenzone, ensulizole, homosalate, meradimate, octinoxate, octisalate, octocrylene, padimate O, sulisobenzone, oxybenzone, avobenzone
- Safety data are not required by the FDA for these 12 ingredients if it can be demonstrated that they are not absorbed under maximum usage conditions.[9]

Possible Options and Recommendations for Action

- Check all ingredients permitted to be used as active ingredients in sunscreens[10]

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[3] https://www.tga.gov.au/behind-news/be-sun-smart-wear-sunscreen

[4] Everything you ever wanted to know about sunscreens (but were afraid to ask). TGA topics, 10 July 2019. https://www.tga.gov.au/blogs/tga-topics/everything-you-ever-wanted-know-about-sunscreens-were-afraid-ask

[5] Matta *et al* (2019). Effect of sunscreen application under maximal use conditions on plasma concentrations of sunscreen active ingredients. A randomised trial. *Journal of the American Medical Association* doi:10.1001/jama.2019.5586

[6] FDA proposes sunscreen regulation changes. February 2019. https://www.fda.gov/media/124654/download ; Proposed rule: https://www.federalregister.gov/documents/2019/02/26/2019-03019/sunscreen-drug-products-for-over-the-counter-human-use

[7] Generally Recognised as Safe and Effective

[8] PEG-PABA and trolamine salicylate (AAN triethanolamine salicylate????) are both on the current Permissible Ingredients determination, although may not be in any sunscreen products on the ARTG; see https://www.legislation.gov.au/Details/F2019L00834/Html/Volume_5

[9] Blood concentrations ≤ 0.5 ng/mL under maximum usage conditions

[10] https://www.legislation.gov.au/series/F2019L00834

- Check TRIM for evidence of safety assessments for these substances, to determine which ones have been grandfathered, and to assess where safety data may be limited
- Compare permissible ingredients against FDA's list of ingredients – is any regulatory action warranted (in particular for PEG-PABA and trolamine salicylate)
- Discuss with COMB to ascertain how the TGA should proceed.
- Consult with external stakeholders.
- Update web advice.
- Set up a literature alert for ingredients whose safety data are limited.
- Conduct a safety assessment for some or all of these ingredients.
- Forge greater links with FDA sunscreen regulators for early alerts on possible safety signals.

Attachment 1: Permitted active ingredients in therapeutic sunscreens[11]

Australian Approved Name (AAN)	Synonyms CAS Number	Maximum Concentration (w/w)
s22		

[11] This information was taken from the 2016 Australian Regulatory Guidelines for Sunscreens (ARGS); this document was updated in August 2019, and will need to be checked against the current Permissible Ingredients determination. For current ARGS see https://www.tga.gov.au/publication/australian-regulatory-guidelines-sunscreens-args

Australian Approved Name (AAN)	Synonyms CAS Number	Maximum Concentration (w/w)
s22		

Australian Approved Name (AAN)	Synonyms CAS Number	Maximum Concentration (w/w)
s22		

Australian Approved Name (AAN)	Synonyms CAS Number	Maximum Concentration (w/w)
s22 [redacted]		
Triethanolamine salicylate	TEA-salicylate [= INCI name] Trolamine salicylate [= INN] CAS No: 2174-16-5	12%
s22 [redacted]		