



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Advertising Approval: Smith and Nephew Pty Ltd – ALLEVYN Life dressings - Exudate-absorbent dressing, non-gel (ARTG 92774)

Therapeutic Goods Act 1989

Approval under section 42DF for use of restricted representations by Smith and Nephew Pty Ltd

I, Michael Shum, as a delegate of the Secretary to the Department of Health and Aged Care, on receipt of an application from Smith and Nephew Pty Ltd, have approved under section 42DF of the *Therapeutic Goods Act 1989*, the restricted representations described in paragraph **(A)**, for use in advertisements for the products identified in paragraph **(B)**, when the statements identified in paragraph **(C)** are prominently displayed and communicated in advertisements in which the restricted representations, paragraph (A), are used (including on the label and packaging of the goods).

(A)

1. Representations to the effect that ALLEVYN Life dressings are for the management of serious wounds, such as [*where one or more of the following wound types are stated*]:
 - pressure sores/injuries/ulcers
 - leg ulcers
 - diabetic foot ulcers
 - skin tears
 - surgical wounds
 - first and second degree burns/superficial and partial thickness burns.
2. Representations to the effect of ALLEVYN Life dressings can help control/manage the moisture in the wound environment, making them suitable for wounds producing low to high amounts of exudate/wound fluid, such as [*where one or more of the following wound types are stated*]:
 - pressure sores/injuries/ulcers
 - leg ulcers
 - diabetic foot ulcers
 - skin tears
 - surgical wounds
 - first- and second-degree burns/superficial and partial thickness burns.
3. Representations to the effect that ALLEVYN Life dressings promote a moist wound environment, which is optimal for the healing of serious wounds, such as [*where one or more of the following wound types are stated*]:
 - leg ulcers

- diabetic foot ulcers
 - skin tears
 - surgical wounds
 - first- and second-degree burns/superficial and partial thickness burns.
4. Representations to the effect that ALLEVYN Life dressings can be used for the management of serious acute and chronic wounds to help them heal, including:
- pressure sores/injuries/ulcers
 - leg ulcers
 - diabetic foot ulcers
 - skin tears
 - surgical wounds
 - first- and second-degree burns/superficial and partial thickness burns.
5. Representations to the effect that ALLEVYN Life dressings can be used to help prevent or delay the onset of pressure sores/ulcers/injuries on intact skin.
6. Representations to the effect that an ALLEVYN Life dressing can be left on a serious wound for up to 5 or 7 days (as indicated in the IFU) before being replaced, with the dressing's change indicator visually showing if it needs to be changed sooner.

(B)

- ALLEVYN Life dressings - Exudate-absorbent dressing, non-gel (ARTG 92774)

(C)

- For representations 1, 2, 3 and 4: The use of these representations must be accompanied by prominently displayed or communicated¹ statements to the effect that (consistent with the Instructions for Use):
 - Allevyn Life dressings can be used by lay persons under the supervision of Healthcare Professionals.
 - If you are concerned about your wound or have any questions about applying, monitoring or removing the dressing, contact your Healthcare Professional.
 - (Where the representation refers to pressure sores/injuries/ulcers) The dressing **must** be used as part of an ongoing pressure ulcer/injury prevention protocol
- For representation 5: The use of the representation must be accompanied by prominently displayed or communicated¹ information advising that the dressing must be used as part of a pressure ulcer/injury prevention protocol. This information must also be included in the IFU.
- For representation 6:
 - This representation must only be used in the context of one or more of the representations above specifying examples of serious wound types for which the use of the dressing is indicated.

¹ ***prominently displayed or communicated***, in relation to a statement in an advertisement, means:

(a) either:

- (i) for a visual statement - easily read from a reasonable viewing distance for the particular media type in the context in which the advertisement is intended to be viewed; or
- (ii) for a spoken statement - able to be clearly heard and understood; and

(b) repeated as often as necessary to be noticed by a viewer or listener.

- The use of the representations will be accompanied by information advising that the dressing should be changed at the earliest of:
 - § when indicated by the change indicator (as per IFU)
 - § as frequently as advised by the patient's health professional, or
 - § the prescribed period as per the IFU (5/7 days)

together, (the **Representations**).

I am satisfied that the Representations are restricted representations as they are representations which will be used in advertisements about therapeutic goods² which refer to 'Pressure sores/injuries/ulcers. Leg ulcers; Diabetic foot ulcers; Skin tears; Surgical wounds; First and second degree burns/superficial and partial thickness burns'. These are all forms of disease, conditions, ailments or defects identified in a part of the Therapeutic Goods Advertising Code as a serious form.

I have decided to approve the use of the Representations as I am satisfied they are accurate and balanced and not misleading or likely to be misleading.

In deciding to approve the use of the Representations I have considered the public interest criteria mentioned in the part of the Therapeutic Goods Advertising Code dealing with restricted representation.

Dated this 30th day of September 2024

Signed electronically

Michael Shum

Delegate of the Secretary to the Department of Health and Aged Care

Advertising and Compliance Education and Policy Section

Regulatory Compliance Branch

² Advertisements to which Part 5-1 of the Act applies.