



Australian Government  
Department of Health and Aged Care  
Therapeutic Goods Administration

**Smith & Nephew Pty Ltd – Allevyn Gentle Border dressings (ARTG 92774)**

***Therapeutic Goods Act 1989***

**Approval under section 42DF for use of restricted representations by Smith & 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 & 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 product identified in paragraph (B), when the statements identified in paragraph (C) are prominently displayed or communicated<sup>1</sup> in the advertisement in which the restricted representations are used (including on the label and packaging of the goods).

**(A)**

1. Representations to the effect that ALLEVYN GENTLE BORDER dressings are for the management of serious wounds [*where one or more of the following wound types are stated*]:
  - § pressure sores/ulcers/injuries
  - § leg ulcers
  - § diabetic foot ulcers
  - § skin tears
  - § surgical wounds
  - § first- and second-degree burns/superficial and partial thickness burns
2. Representations to the effect that ALLEVYN GENTLE BORDER dressings can help control/manage the moisture in the wound environment and are suitable for wounds producing moderate amounts of exudate/wound fluid, including [*where one or more of the following wound types are stated*]:
  - § pressure sores/ulcers/injuries
  - § leg ulcers
  - § diabetic foot ulcers
  - § skin tears
  - § surgical wounds
  - § first- and second-degree burns/superficial and partial thickness burns

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<sup>1</sup> ***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

3. Representations to the effect that ALLEVYN GENTLE BORDER 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*]
  - § pressure sores/ulcers/injuries
  - § 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 GENTLE BORDER 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 GENTLE BORDER dressings can be used to help prevent pressure sores/ulcers/injuries on intact skin.
6. Representations to the effect that an ALLEVYN GENTLE BORDER 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 level of exudate visible on the outer surface of the dressing providing an indication of whether it needs to be changed sooner.

**(B)**

- ALLEVYN Gentle Border dressings (ARTG 92774)

**(C)**

- For representations 1, 2, 3 and 4: The use of these representations will be accompanied by prominently displayed or communicated statements (consistent with the instructions for use) to the effect that:
  - Allevyn GENTLE BORDER 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 representations will be accompanied by prominently displayed or communicated information advising that the dressing must be used as part of a pressure ulcer/injury prevention protocol. This information is also included in the IFU.
- For representation 6:
  - This representation will 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.
  - 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 wound break through on the dressing pad (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**).

Dated this 17 th day of October 24

*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