



Australian Government  
Department of Health and Aged Care  
Therapeutic Goods Administration

## Advertising Approval: Coloplast Pty Ltd – Biatain Adhesive Dressings - Dressing, high-absorbent, foam/sheet/liquid/powder, non-hydrophilic gel-forming (ARTG 140299)

### ***Therapeutic Goods Act 1989***

#### **Approval under section 42DF for use of restricted representations by Coloplast Pty Ltd**

I, Rowena Love, as a delegate of the Secretary to the Department of Health and Aged Care, on receipt of an application from Coloplast 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), subject to the conditions identified in paragraph **(D)**.

#### **(A)**

1. Representations to the effect that Biatain Adhesive dressings can be used for the management of serious acute and chronic wounds to help them heal, such as [*where one or more of the following wound types are stated*]:
  - § pressure sores/injuries/ulcers
  - § leg ulcers
  - § Postoperative wounds & traumatic wounds
  - § first and second degree burns/superficial and partial thickness burns.
2. Representations to the effect of Biatain Adhesive 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
  - § Postoperative wounds & traumatic 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 Biatain Adhesive 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/injuries/ulcers
  - § leg ulcers
  - § Postoperative wounds & traumatic wounds
  - § first and second degree burns/superficial and partial thickness burns.
4. Representations to the effect that Biatain Adhesive foam dressings can conform to the wound bed up to 2 centimetres deep in serious acute and chronic wounds to help them heal, including:
  - § pressure sores/injuries/ulcers
  - § leg ulcers
  - § Postoperative wounds & traumatic wounds
  - § first and second degree burns/superficial and partial thickness burns.
5. Representations to the effect that an Biatain Adhesive dressings can be left on a serious wound for up to 7 days before being replaced.

**(B)**

- Biatain Adhesive Dressings - Dressing, high-absorbent, foam/sheet/liquid/powder, non-hydrophilic gel-forming [ARTG 140299].

**(C)**

- For representations (A)1, 2, 3 and 4: The use of these representations must be accompanied by prominently displayed or communicated<sup>2</sup> statements to the effect that:
  - Biatain Adhesive 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 (A) 5:
  - 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.
  - The use of the representations will be accompanied by information advising that the dressing should be changed at the earliest of:
    - § a time and ongoing frequency as advised by the patient's health professional, or
    - § the prescribed period as per the IFU (7 days)

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<sup>2</sup> ***prominently displayed or communicated***, in relation to a statement in an advertisement, means:

(a) either:

- (ii) 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.

**(D)**

- Advertisements in which any one of the restricted representations specified in paragraph **(A)**1.- 5. is used must comply with the Therapeutic Goods Advertising Code.

Dated this 24<sup>th</sup> day of April 2025

*Signed electronically*

Rowena Love

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

Advertising and Compliance Education and Policy Section

Regulatory Compliance Branch