Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Advertising Approval: Coloplast Pty Ltd – Biatain Silicone - 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, Michael Shum, 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[1] 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 Silicone 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 / post operative wounds
   - first- and second-degree burns/superficial and partial thickness burns
2. Representations to the effect of Biatain Silicone 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

[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

- surgical wounds / post operative wounds
- first and second degree burns/superficial and partial thickness burns

3. Representations to the effect that Biatain Silicone 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
   - diabetic foot ulcers
   - skin tears
   - surgical wounds / post operative wounds
   - first- and second-degree burns/superficial and partial thickness burns
4. Representations to the effect that Biatain Silicone 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 / post operative wounds
   - first- and second-degree burns/superficial and partial thickness burns
5. Representations to the effect that Biatian Silicone dressing can be left on a serious wound for up to 7 days (as indicated in the IFU) before being replaced.
   - 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.

(B)

· Biatain Silicone - Dressing, high-absorbent, foam/sheet/liquid/powder, non-hydrophilic gel-forming (ARTG 140299)

(C)

· For representations 1, 2, 3 and 4: The use of these representations must be accompanied by prominently displayed or communicated statements to the effect that (consistent with the Instructions for Use):
   - Biatain Silicone 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 information advising that the dressing should be changed when clinically indicated, when visible signs of exudate approaching the edge of the foam or after 7 days.

(D)

- Advertisements in which any one of the Approved Representations is used must comply with the Therapeutic Goods Advertising Code (the Code).

Dated this 25th day of February 25

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