



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Molnlycke Health Care Pty Ltd - Mepilex Heel Ag - Wound-nonadherent dressing, absorbent, antimicrobial (ARTG 210027)

Therapeutic Goods Act 1989

Approval under section 42DF for use of restricted representations by Molnlycke Health Care Pty Ltd

I, Rowena Love, as a delegate of the Secretary to the Department of Health, Disability and Ageing, on receipt of an application from Molnlycke Health Care Pty Ltd, have approved under section 42DF of the *Therapeutic Goods Act 1989*, the restricted representation to the effect of that 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 communicated¹ in the advertisement in which the restricted representations are used.

(A)

Mepilex Heel Ag is intended for use on the following low to moderate fluid wounds, including infected wounds and those showing signs of infection:

- leg and foot ulcers
- pressure ulcers/injuries
- partial thickness burns.

(B)

Mepilex Heel Ag - Wound-nonadherent dressing, absorbent, antimicrobial (ARTG 210027).

(C)

- Mepilex Heel Ag must be used under the supervision of a qualified Healthcare Professional
- If you are concerned about your wound, please contact your Healthcare Professional.

Dated this 18th day of June 26

Signed electronically

Rowena Love

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

*Delegate of the Secretary to the Department of Health, Disability and Ageing
Education Policy and Guidance Section
Regulatory Compliance Branch*