



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Molnlycke Health Care Pty Ltd – Melgisorb Ag - Dressing, highly-absorbent, hydrophilic gel-forming, antimicrobial (ARTG 308789)

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 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 advertisements in which the restricted representation is used.

(A)

Melgisorb Ag is intended for use on the following: medium to high fluid wounds, including those showing signs of infection.

- venous leg ulcers
- diabetic foot ulcers
- pressure injuries.

(B)

Melgisorb Ag - Dressing, highly-absorbent, hydrophilic gel-forming, antimicrobial (ARTG 308789)

(C)

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

Dated this 17th day of June 26

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

Signed electronically

Rowena Love

Delegate of the Secretary to the Department of Health, Disability and Ageing

Education Policy and Guidance Section

Regulatory Compliance Branch