



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Smith & Nephew Pty Ltd – Skin cleanser (ARTG 357015) and Skin moisturizing/barrier dressing (ARTG 357016)

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, Disability and Ageing, 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 **(C)**. Additionally, I have approved the use of the restricted representations identified in paragraph **(B)**, in advertisements about the products identified in paragraph **(C)**, when the statement identified in paragraph **(D)** is prominently displayed or communicated¹ in the advertisement in which the restricted representations are used.

(A)

- Representations to the effect that Proshield Plus Skin Protectant helps prevent skin from breaking down/skin irritation due to urinary or faecal incontinence exposure.
- Representations to the effect that Proshield Plus Skin Protectant helps prevent incontinence associated dermatitis/rash caused by incontinence.
- Representations to the effect that Proshield Plus Skin Protectant helps prevent chafed, chapped and cracked skin from incontinence associated dermatitis/rash caused by incontinence.
- Representations to the effect that Proshield Plus Skin Protectant protects chafed, chapped and cracked skin in incontinence associated dermatitis/rash caused by incontinence.
- Representations to the effect that Proshield Plus Skin Protectant helps treat/manage incontinence-associated dermatitis/rash caused by incontinence.
- Representations to the effect that Proshield Foam & Spray Incontinence Cleanser is suitable for use on skin affected by incontinence (including implied claims such as through trade name Proshield Foam & Spray Incontinence Cleanser).
- Representations to the effect that Proshield Foam & Spray Incontinence Cleanser is for cleansing intact or injured skin exposed to urinary or faecal incontinence.

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

- Representations to the effect that Proshield Foam & Spray Incontinence Cleanser is for cleansing intact or injured skin exposed to common severe or chronic diarrhoea.
- Use of Proshield Foam & Spray Incontinence Cleanser, followed by Proshield Plus Skin Protectant, can prevent incontinence-associated dermatitis/rash caused by incontinence.
- Use of Proshield Foam & Spray Incontinence Cleanser, followed by Proshield Plus Skin Protectant, can treat/manage incontinence-associated dermatitis/rash caused by incontinence.
- Representations to the effect that, by helping to maintain skin integrity, Proshield products can help reduce the risk of pressure ulcers when used as part of a pressure ulcer prevention program.
- Representations to the effect that Proshield Plus Skin Protectant is not to be used over infections or deep wounds.

(B)

- Representations that refer to IAD/rash caused by incontinence, pressure ulcers or skin infections in accurate, balanced, contemporary and non-promotional information, the purpose of which is to educate consumers, in plain language, about these conditions.

(C)

- Smith & Nephew Pty Ltd - Skin moisturizing/barrier dressing (ARTG 357016)
- Smith & Nephew Pty Ltd - Skin cleanser (ARTG 357015)

(D)

- If you are concerned about any of these matters, contact your Healthcare Professional.

Dated this 3rd day of June 26

Signed electronically

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