

30th April 2024

Dear Healthcare Professional,

Availability of LYCLEAR SCABIES CREAM (AUST R 46343) - alternative supply arrangement under Section 19A of the Therapeutic Goods Act.

Due to shortage of the Australian registered LYCLEAR SCABIES CREAM (AUST R 46343), Reach Pharmaceuticals has arranged the supply of an alternative product called **PERMETHRIN - permethrin cream 5% w/w cream (Encube)** registered and marketed in the USA.

PERMETHRIN - permethrin cream 5% w/w cream (Encube) is not registered in Australia and supply is authorised under an exemption granted by the Therapeutic Goods Administration (TGA) under Section 19A of the *Therapeutic Goods Act*, 1989 until 31st October 2024 for the following indications:

For the treatment of infestation with sarcoptes scabiei (scabies).

The dosage instructions and directions for use approved in Australia should be used when applying the alternative USA product. These instructions are:

Directions for use:

Adults and children 2 years and over: Apply cream to the whole body except the head and face. The cream should be left on for at least 8 hours, then washed off with soap and water.

Dosage:

Adults and children over 12 years: Up to 30 g

Children: 5 to 12 years: Up to 15 g

1 to 5 years: Up to 7.5 g

6 months to 1 year: Up to 3.75 g

A few adults may need to use more than 30 g, but do not apply more than 60 g.

The S19A approved USA product is identical in active ingredient and strength to the Australian registered product. A comparison table of differences between excipients is given in the table below:

	ARTG products	S19A products
	LYCLEAR SCABIES CREAM (AUST R 46343) – 30g	PERMETHRIN - permethrin cream 5% w/w cream (Encube) – 60g



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Excipients	butylated hydroxytoluene carbomer 934P ceteth-2 cetomacrogol 1000 formaldehyde solution fractionated coconut oil glycerol glyceryl monostearate isopropyl myristate liquid paraffin purified water sodium hydroxide Wool alcohols	Carbomer homopolymer type B, medium-chain triglycerides, glycerin, mono-and diglycerides, isopropyl myristate, lanolin alcohols, mineral oil, polyoxyethylene (20) cetyl ethers, purified water, and sodium hydroxide. Formaldehyde 1 mg (0.1%) is added as a preservative.
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Adverse Event Reporting

Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **PERMETHRIN - permethrin cream 5% w/w cream (Encube)** should be reported by healthcare professionals and patients to our Medical Information. This information can also be reported to the TGA at <https://www.tga.gov.au/reporting-problems>.

Reach Pharmaceuticals Medical Information can be contacted by phone on 1800 505 306 or via email at medical@reach-pharma.com

For sales related enquiries, please contact us on sales@reach-pharma.com or call 0422 429 648.

We would appreciate if you could distribute this information to those in your organisation who prescribe the product.

Yours sincerely,

Reach Pharmaceuticals Pty Ltd