

30<sup>th</sup> 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 31<sup>st</sup> 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                                                    |
|--|---------------------------------------------------|------------------------------------------------------------------|
|  | <b>LYCLEAR SCABIES CREAM (AUST R 46343) – 30g</b> | <b>PERMETHRIN - permethrin cream 5% w/w cream (Encube) – 60g</b> |



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|                   |                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                        |
|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Excipients</b> | butylated hydroxytoluene<br>carbomer 934P<br>ceteth-2<br>cetomacrogol 1000<br>formaldehyde solution<br>fractionated coconut oil<br>glycerol<br>glyceryl monostearate<br>isopropyl myristate<br>liquid paraffin<br>purified water<br>sodium hydroxide<br>Wool alcohols | Carbomer homopolymer type B,<br>medium-chain triglycerides,<br>glycerin, mono-and diglycerides,<br>isopropyl myristate, lanolin alcohols,<br>mineral oil,<br>polyoxyethylene (20) cetyl ethers,<br>purified water, and sodium<br>hydroxide. Formaldehyde<br>1 mg (0.1%) is added as a<br>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](mailto:medical@reach-pharma.com)

**For sales related enquiries, please contact us on [sales@reach-pharma.com](mailto: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