



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	357688	WoundGel 800+
ARTG entry for	Medicine Listed	
Sponsor	Manuka Life Holdings Pty Ltd	
Postal Address	22 Margaret Street, Cottesloe, WA, 6011 Australia	
ARTG Start Date	25/03/2021	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products

1 . WoundGel 800+

Product Type	Single Medicine Product	Effective Date	17/12/2021
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Permitted Indications

- Decrease/reduce/relieve symptoms of mild, superficial skin fungal infections
- Decrease/reduce/relieve symptoms of athlete's foot/tinea
- Helps enhance/promote skin regeneration
- Helps decrease/reduce/relieve symptoms of minor skin wounds (cuts, scratches and abrasions)
- Helps healing of mild skin burn/sunburns
- Antimicrobial for minor cuts and abrasions
- Antiseptic for minor cuts and abrasions
- Enhance/improve healing of minor skin wound/cuts/scratches/abrasions
- Enhance/improve/promote skin healing
- Maintain/support wound healing
- Decrease/reduce/relieve symptoms of insect bite/sting
- Aids/assists healing of minor skin pressure sores (decubitus ulcers/bedsores)
- Enhance/improve/promote skin repair/healing

Indication Requirements

- Product presentation must only refer to mild fungal infection.
- Label statement: If symptoms persist, talk to your health professional.
- If product is indicated for skin burn, Label statement: Only to be used for minor burns after initial first aid treatment, medical advice should be sought for serious burns.
- Product presentation must not imply or refer to serious infections.
- Product presentation must only refer to 'mild' burns.
- If product is indicated for skin burn, Label statement: Immediate treatment of burns should be application of cold water for ten minutes (or words to that effect).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

