



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	409944	Hamilton Urederm
ARTG entry for	Medicine Listed	
Sponsor	Key Pharmaceuticals Pty Ltd	
Postal Address	PO Box 1033, NORTH RYDE BC, NSW, 1670 Australia	
ARTG Start Date	2/06/2023	
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 . Hamilton Urederm

Product Type	Single Medicine Product	Effective Date	2/06/2023
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Permitted Indications

Decrease/reduce/relieve symptoms of mild eczema/dermatitis
Helps reduce occurrence of symptoms of eczema/dermatitis
Decrease/reduce/relieve symptoms of mild psoriasis
Decrease/reduce/relieve skin dryness
Soothe skin
Decrease/reduce/relieve skin scaling/crusty skin
Helps reduce occurrence of skin dryness
Helps enhance/improve/promote/increase skin hydration
Maintain/support skin hydration
Maintain/support skin elasticity
Helps enhance/improve skin elasticity
Helps enhance/improve skin strength

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.
Product presentation must only refer to mild psoriasis
Product presentation must only refer to mild eczema.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains hydroxybenzoates (or words to this effect) if the medicines contains more than one hydroxybenzoate source OR Contains (insert the approved name of hydroxybenzoate used)(or words to this effect) if product contains one hydroxybenzoate source.

Additional Product information

Pack Size/Poison information

