



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	179095	Necessity Fixaderm Lotion
ARTG entry for	Medicine Listed	
Sponsor	Launoy Health Products Pty Ltd	
Postal Address	Unit 4 / 113 Scarborough Street, Southport, QLD, 4215 Australia	
ARTG Start Date	12/01/2011	
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . Necessity Fixaderm Lotion

Product Type	Single Medicine Product	Effective Date	28/08/2019
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Permitted Indications

Decrease/reduce/relieve symptoms of mild eczema/dermatitis
Soothe/relieve skin inflammation
Decrease/reduce/relieve skin irritation
Decrease/reduce skin sensitivity
Enhance/improve healing of minor skin wound/cuts/scratches/abrasions
Maintain/support wound healing
Decrease/reduce/relieve symptoms of insect bite/sting
Enhance/improve/promote skin repair/healing

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.
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

If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

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Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Multiple containers	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Lotion
Route of Administration	Topical

Visual Identification

Active Ingredients

Calendula officinalis flower Oil infused	8.34 microlitre/mL
Lavender Oil	8.34 microlitre/mL
Melaleuca Oil	10.86 microlitre/mL
Pogostemon cablin leaf Oil essential	9.16 microlitre/mL
Rosa eglanteria seed Oil fixed	6.66 microlitre/mL

Other Ingredients (Excipients)

- Almond oil
- Aniba rosaeodora
- Camellia oleifera
- Evening Primrose Oil
- Melaleuca quinquenervia
- Simmondsia chinensis

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