



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	13397	Lucas' Papaw Ointment
ARTG entry for	Medicine Listed	
Sponsor	Lucas Papaw Remedies	
Postal Address	1590 Beaudesert Road, ACACIA RIDGE, QLD, 4110 Australia	
ARTG Start Date	5/09/1991	
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 . Lucas' Papaw Ointment

Product Type	Single Medicine Product	Effective Date	24/01/2022
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Permitted Indications

- Decrease/reduce/relieve skin dryness
- Decrease/reduce/relieve skin peeling/cracking
- Decrease/reduce/relieve skin chafing
- Soothes/relieves heat rash
- Decrease/reduce/relieve symptoms of nappy rash
- Relieve red skin rash
- Helps decrease/reduce/relieve symptoms of minor skin wounds (cuts, scratches and abrasions)
- Soothe/relieve mild skin burn/sunburns
- Decrease/reduce/relieve symptoms of insect bite/sting

Indication Requirements

- 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.
- 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).
- Product presentation must only refer to 'mild' burns.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Ointment

Route of Administration Topical

Visual Identification

Active Ingredients

Carica papaya fruit Fresh 39 mg/g

Other Ingredients (Excipients)

hard paraffin

Peru Balsam

potassium sorbate

yellow soft paraffin

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