



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	229440	Calendula Cream
ARTG entry for	Medicine Listed	
Sponsor	Martin & Pleasance Pty Ltd	
Postal Address	PO Box 2007, SOUTH MELBOURNE, VIC, 3205 Australia	
ARTG Start Date	16/10/2014	
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 . Calendula Cream

Product Type	Single Medicine Product	Effective Date	22/01/2020
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Permitted Indications

Traditionally used in European herbal medicine to enhance/improve/promote healing of bruises

Traditionally used in European herbal medicine to decrease/reduce/relieve symptoms of mild eczema/dermatitis

Linked indication - Antipruritic/Relieves itchy skin

Linked indication - Decrease/reduce/relieve skin dryness

Linked indication - Decrease/reduce/relieve itchy/prickling skin associated with mild eczema/dermatitis

Traditionally used in European herbal medicine to decrease/reduce/relieve symptoms of boils

Linked indication - Maintain/support wound healing

Linked indication - Soothe/relieve skin inflammation

Traditionally used in European herbal medicine to soothe/relieve skin inflammation

Traditionally used in European herbal medicine to decrease/reduce/relieve skin irritation

Traditionally used in European herbal medicine to decrease/reduce/relieve symptoms of nappy rash

Linked indication - Relieve red skin rash

Linked indication - Antipruritic/Relieves itchy skin

Traditionally used in European herbal medicine to vulnerary/wound healing

Traditionally used in Eastern European herbal medicine to vulnerary/wound healing

Traditionally used in European herbal medicine to helps healing of mild skin burn/sunburns

Traditionally used in European herbal medicine to soothe/relieve mild skin burn/sunburns

Traditionally used in European herbal medicine to antiseptic for minor cuts and abrasions

Traditionally used in European herbal medicine to enhance/improve healing of minor skin wound/cuts/scratches/abrasions

Traditionally used in European herbal medicine to aids/assists healing of minor skin pressure sores (decubitus ulcers/bedsores)

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.



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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 eczema.

Product presentation must not imply or refer to serious infections.

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

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

Contains ethanol or contains alcohol.

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Cream

Route of Administration Topical

Visual Identification

Active Ingredients

Calendula officinalis flower Extract liquid	100 microlitre/g
Equivalent: Calendula officinalis (Dry)	20 mg/g

Other Ingredients (Excipients)

Carnauba Wax
Castor Oil
cetearyl glucoside
cetostearyl alcohol
citric acid monohydrate
gluconolactone
glycerol
glyceryl caprylate
hydrogenated castor oil
medium chain triglycerides
p-anisic acid
purified water
Rice bran oil
self-emulsifying glyceryl monostearate
sodium hydroxide
sodium stearyl glutamate
white beeswax
xanthan gum

Public Summary

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