



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 237703 **Tea Tree Cream**

ARTG entry for Medicine Listed
Sponsor Martin & Pleasance Pty Ltd
Postal Address PO Box 2007, SOUTH MELBOURNE, VIC, 3205 Australia
ARTG Start Date 14/05/2015
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 . Tea Tree Cream

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

Traditionally used in Western herbal medicine to relieve symptoms of acne
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of boils
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild, superficial skin fungal infections
Traditionally used in Western herbal medicine to decrease/reduce/relieve skin burning/itching associated with athlete's foot/tinea
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of athlete's foot/tinea
Traditionally used in Western herbal medicine to antiseptic for minor cuts and abrasions
Traditionally used in Western herbal medicine to enhance/improve healing of minor skin wound/cuts/scratches/abrasions
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of insect bite/sting

Indication Requirements

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

Product presentation must not imply or refer to serious infections.

Product presentation must only refer to mild fungal infection.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product Information



Australian Government
Department of Health
Therapeutic Goods Administration

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Cream
Route of Administration Topical

Visual Identification

Active Ingredients

Melaleuca Oil 50 microlitre/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 stearoyl glutamate

white beeswax

xanthan gum

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