



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	237703	Tea Tree Cream
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Martin & Pleasance Pty Ltd	
<b>Postal Address</b>	PO Box 2007, SOUTH MELBOURNE, VIC, 3205 Australia	
<b>ARTG Start Date</b>	14/05/2015	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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

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**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

<b>Dosage Form</b>	Cream
<b>Route of Administration</b>	Topical

**Visual Identification**

**Active Ingredients**

<b>Melaleuca Oil</b>	<b>50 microlitre/g</b>
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**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

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