



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	55740	THURSDAY PLANTATION TEA TREE MEDICATED GEL FOR ACNE
ARTG entry for	Medicine Listed	
Sponsor	Integria Healthcare Australia Pty Ltd	
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
ARTG Start Date	2/04/1996	
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 . THURSDAY PLANTATION TEA TREE MEDICATED GEL FOR ACNE

Product Type	Single Medicine Product	Effective Date	1/08/2019
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Permitted Indications

- Relieve symptoms of acne
- Relieve minor skin eruptions
- Decrease/reduce/relieve symptoms of acne blackheads
- Helps reduce occurrence of blackheads
- Helps reduce occurrence of symptoms of acne
- Decrease/reduce/relieve pimples
- Helps reduce occurrence of pimples
- Soothe/relieve skin inflammation

Indication Requirements

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

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 words to that effect).

Additional Product information



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Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form Gel
Route of Administration Topical

Visual Identification

Active Ingredients

Melaleuca Oil	200 mg/g
Equivalent: cineole	12 mg/g
Equivalent: Cajuput Oil	0 mg/g

Other Ingredients (Excipients)

carbomer 940
ethanol
isopropyl myristate
polysorbate 60
purified water
racemic camphor
trolamine

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