



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	295668	Thursday Plantation Tea Tree & Manuka Honey Healing Balm
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	30/10/2017	
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 & Manuka Honey Healing Balm

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

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Aid/assist in the healing of minor body tissue injuries
Maintain/support body tissue repair/regeneration
Soothe/relieve skin inflammation
Decrease/reduce/relieve skin irritation
Maintain/support skin regeneration
Helps decrease/reduce/relieve symptoms of minor skin wounds (cuts, scratches and abrasions)
Cleanse minor skin wound/cuts/scratches/abrasions
Antimicrobial for minor cuts and abrasions
Antiseptic for minor cuts and abrasions
Maintain/support wound healing
Decrease/reduce/relieve symptoms of insect bite/sting
Maintain/support skin repair/healing/regeneration

Indication Requirements

Product presentation must not imply or refer to serious infections.
Label statement: If symptoms persist, talk to your health professional.

Standard Indications

No Standard Indications included on Record

Specific Indications



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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.

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

Contains benzoates' (or words to this effect) if the medicine contains two or more benzoate sources or 'Contains [insert the approved name of benzoate used]' (or words to this effect) if product contains one benzoate source.

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Gel
Route of Administration Topical

Visual Identification

Active Ingredients

Honey	200 mg/g
Melaleuca Oil	50 mg/g

Other Ingredients (Excipients)

Almond oil
Calendula officinalis
cetearyl glucoside
cetostearyl alcohol
hypromellose
lactic acid
potassium sorbate
purified water
sodium benzoate
Sunflower Oil

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