



**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	Effective Date
Single Medicine Product	1/08/2019

#### 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

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

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications



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No Specific Indications included on Record

**Warnings**

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

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.

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**

<b>Honey</b>	<b>200 mg/g</b>
<b>Melaleuca Oil</b>	<b>50 mg/g</b>

**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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