



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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| Summary for ARTG Entry: | 166190 | Thursday Plantation Tea Tree Antiseptic Spray with Aloe Vera |
| 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 | 20/10/2009 | |
| 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.

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 Antiseptic Spray with Aloe Vera

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 18/03/2020 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

Decrease/reduce/relieve symptoms of mild, superficial skin fungal infections
Helps decrease/reduce/relieve symptoms of minor skin wounds (cuts, scratches and abrasions)
Traditionally used in Western herbal medicine to helps decrease/reduce/relieve symptoms of minor skin wounds (cuts, scratches and abrasions)
Traditionally used in Western herbal medicine to cleanse minor skin wound/cuts/scratches/abrasions
Cleanse minor skin wound/cuts/scratches/abrasions
Traditionally used in Western herbal medicine to antimicrobial for minor cuts and abrasions
Antimicrobial for minor cuts and abrasions
Traditionally used in Western herbal medicine to antiseptic for minor cuts and abrasions
Antiseptic for minor cuts and abrasions
Decrease/reduce/relieve symptoms of insect bite/sting
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 only refer to mild fungal infection.
Product presentation must not imply or refer to serious infections.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains ethanol or contains alcohol.
If symptoms persist consult your healthcare practitioner (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 | Spray |
| Route of Administration | Topical |
| Visual Identification | |
| Active Ingredients | |
| Melaleuca Oil | 150 mg/g |
| Other Ingredients (Excipients) | |
| Aloe vera | |
| ethanol | |
| polysorbate 60 | |
| polysorbate 80 | |
| purified water | |

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