

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 295668 Thursday Plantation Tea Tree & Manuka Honey Healing Balm

ARTG entry for Medicine Listed

Sponsor Homart Wellness Aust Pty Ltd

Postal Address 59 Kirby Street, Rydalmere, NSW, 2116

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.

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 17/12/2024

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

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.

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Additional Product information

Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage FormGelRoute of AdministrationTopical

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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