

### **Australian Government**

### **Department of Health and Aged Care**

Therapeutic Goods Administration

### **Public Summary**

Summary for ARTG Entry: 259986 Thursday Plantation Tea Tree Anti-Fungal Solution for Nails

ARTG entry for Medicine Listed

Sponsor Homart Wellness Aust Pty Ltd

Postal Address 59 Kirby Street, Rydalmere, NSW, 2116

Australia

ARTG Start Date 15/09/2015
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 Anti-Fungal Solution for Nails

Product Type Single Medicine Product Effective Date 17/12/2024

### **Permitted Indications**

Decrease/reduce/relieve symptoms of mild, superficial skin fungal infections

#### **Indication Requirements**

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

Product presentation must only refer to mild fungal infection.

#### 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).

#### Additional Product information

## Pack Size/Poison information

Pack Size Poison Schedule

#### Components

### 1 . Formulation 1

Visual Identification

### **Active Ingredients**

Melaleuca Oil 50 mg/g

# Other Ingredients (Excipients)

Litsea cubeba

macrogol 300

### Page 1 of 2



## **Department of Health and Aged Care**

Therapeutic Goods Administration

undecenoic acid

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