Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 311785 Thursday Plantation Sleep Support & Calming Lavender Oil Roll On

ARTG entry for Medicine Listed

Sponsor Homart Wellness Aust Pty Ltd

Postal Address 59 Kirby Street, Rydalmere, NSW, 2116

Australia

ARTG Start Date 21/11/2018
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 Sleep Support & Calming Lavender Oil Roll On

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

Permitted Indications

Support healthy stress response in the body

Calms the mind

Traditionally used in Aromatherapy to calms the mind

Traditionally used in Aromatherapy to decrease/reduce/relieve restlessness/excess nervous energy

Soothe/calm nerves

Traditionally used in Aromatherapy to soothe/calm nerves

Traditionally used in Aromatherapy to decrease/reduce/relieve symptoms of stress

Traditionally used in Aromatherapy to decrease/reduce/relieve nervous tension/unrest

Traditionally used in Aromatherapy to decrease/reduce/relieve symptoms of mild anxiety

Traditionally used in Aromatherapy to calmative/nervous system relaxant

Traditionally used in Aromatherapy to nervine/support nervous system

Traditionally used in Aromatherapy to soporific/induces sleep

Traditionally used in Aromatherapy to decrease/reduce/relieve sleeplessness

Traditionally used in Aromatherapy to decrease/reduce/relieve disturbed/restless sleep

Traditionally used in Aromatherapy to maintain/support healthy sleeping patterns

Maintain/support healthy sleeping patterns

Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

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

Product presentation must only refer to mild anxiety.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

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Department of Health and Aged Care

Therapeutic Goods Administration

Additional Product information					
Pack Size/Poison information					
Pack Size			Poison Schedule		
Components					
1 . Formulation 1					
Dosage Form	Application				
Route of Administration	Topical				
Visual Identification					
Active Ingredients					
Lavender Oil				100 mg/g	
Other Ingredients (Excipients)					

medium chain triglycerides

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