



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	Integria Healthcare Australia Pty Ltd	
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 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.

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 Sleep Support & Calming Lavender Oil Roll On

Product Type	Single Medicine Product	Effective Date	14/06/2019
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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

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

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

Product presentation must only refer to mild anxiety.



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Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Application

Route of Administration Topical

Visual Identification

Active Ingredients

Lavender Oil	100 mg/g
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Other Ingredients (Excipients)

medium chain triglycerides

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