



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	311787	Thursday Plantation Headache Pain Relief Peppermint Oil Roll On
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Integria Healthcare Australia Pty Ltd	
<b>Postal Address</b>	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
<b>ARTG Start Date</b>	21/11/2018	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 Headache Pain Relief Peppermint Oil Roll On

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	21/11/2018
---------------------	-------------------------	-----------------------	------------

#### Permitted Indications

Traditionally used in Western herbal medicine to decrease/reduce/relieve headache symptoms

Traditionally used in Western herbal medicine to helps reduce occurrence of symptoms of headaches

Traditionally used in Western herbal medicine to decrease/reduce headache duration

Traditionally used in Western herbal medicine to helps decrease/reduce/relieve symptoms of mild tension headache

#### Indication Requirements

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

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

If irritation develops, discontinue use.

If you have sensitive skin, test this product on a small area of skin before applying it to a large area.

If symptoms persist consult your healthcare practitioner (or words to that effect).

Avoid contact with eyes (or words to that effect).

#### Additional Product information

#### Pack Size/Poison information

<b>Pack Size</b>	<b>Poison Schedule</b>
------------------	------------------------

