



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

## Public Summary

<b>Summary for ARTG Entry:</b>	287407	Thompson's One-A-Day Valerian 2000
<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>	2/04/2017 11:00:00 PM	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Listed Medicines	

### Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

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 . Thompson's One-A-Day Valerian 2000

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	5/02/2021
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### Permitted Indications

- Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal spasm
- Traditionally used in Western herbal medicine to decrease/reduce/relieve digestive spasms
- Traditionally used in Western herbal medicine to antispasmodic/spasmolytic
- Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of stress
- Traditionally used in Western herbal medicine to decrease/reduce/relieve nervous tension/unrest
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild anxiety
- Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness
- Traditionally used in Western herbal medicine to decrease/reduce/relieve disturbed/restless sleep

### Indication Requirements

- Product presentation must not imply or refer to gastro oesophageal reflux disease.
- 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.
- Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

### 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



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Pack Size

Poison Schedule

**Components**

**1 . Formulation 1**

**Dosage Form** Capsule, hard

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Valeriana officinalis root and rhizome Extract dry concentrate standardised</b>	<b>400 mg</b>
Equivalent: Valeriana officinalis (Dry)	2000 mg

**Other Ingredients (Excipients)**

colloidal anhydrous silica  
disodium edetate  
gellan gum  
hypromellose  
magnesium stearate  
microcrystalline cellulose  
potable water  
potassium acetate  
sodium starch glycollate

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Public Summary