



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

## Public Summary

<b>Summary for ARTG Entry:</b>	377735	Thompson's One-A-Day St John's Wort 4000
<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>	10/11/2021	
<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 St John's Wort 4000

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	10/11/2021
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### Permitted Indications

Traditionally used in Western herbal medicine to help maintain/support emotional wellbeing  
Help maintain/support emotional wellbeing  
Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy  
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  
Decrease/reduce/relieve symptoms of mild anxiety  
Helps reduce occurrence of symptoms of mild anxiety  
Traditionally used in Western herbal medicine to helps reduce occurrence of symptoms of mild anxiety  
Traditionally used in Western herbal medicine to maintain/support nervous system health  
Support healthy emotional/mood balance  
Traditionally used in Western herbal medicine to support healthy emotional/mood balance  
Traditionally used in Western herbal medicine to decrease/reduce/relieve mild nerve pain/neuralgia  
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild sciatica  
Decrease/reduce/relieve mood changes/mood swings associated with premenstrual tension  
Decrease/reduce/relieve symptoms of premenstrual tension

### Indication Requirements

Label statement: If symptoms persist, talk to your health professional.  
Product presentation must only refer to mild nerve pain/neuralgia.  
Product presentation must not imply or refer to mental illnesses, disorders or conditions.  
Product presentation must only refer to mild sciatica.  
Product presentation must only refer to mild anxiety.

### Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record

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#### Warnings

St John's Wort affects the way many prescription medicines work, including the oral contraceptive pill. Consult your doctor.  
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

**Dosage Form** Tablet, film coated

**Route of Administration** Oral

##### Visual Identification

#### Active Ingredients

**Hypericum perforatum herb top flowering Extract dry concentrate standardised** 666.67 mg

Equivalent: Hypericum perforatum (Dry) 4 g

#### Other Ingredients (Excipients)

colloidal anhydrous silica

croscarmellose sodium

hypromellose

iron oxide black

iron oxide red

iron oxide yellow

macrogol 400

magnesium stearate

microcrystalline cellulose

sodium starch glycollate

titanium dioxide

vanillin

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