Public Summary

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

Product Type Single Medicine Product **Effective Date** 5/02/2021

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

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

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	Capsule, hard
Route of Administration	Oral
Visual Identification	

Active Ingredients

Valeriana officinalis root and rhizome Extract dry concentrate standardised	**400 mg**
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