



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	377116	Thompson's Ashwagandha Complex Stress + Sleep
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	29/10/2021	
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.

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 Ashwagandha Complex Stress + Sleep

Product Type	Single Medicine Product	Effective Date	29/10/2021
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Permitted Indications

- Traditionally used in Ayurvedic medicine to rasayan/rejuvenative tonic
- Traditionally used in Ayurvedic medicine to balance Vata
- Traditionally used in Ayurvedic medicine to balance aggravated Vata
- Traditionally used in Ayurvedic medicine to aids/assists with recovery from illness/convalescence in healthy elderly individuals
- Traditionally used in Ayurvedic medicine to aids/assists with recovery from illness/convalescence In older females
- Traditionally used in Ayurvedic medicine to aids/assists with recovery from illness/convalescence In older males
- Traditionally used in Ayurvedic medicine to relieve feelings of general malaise/general debility In older males
- Traditionally used in Ayurvedic medicine to relieve feelings of general malaise/general debility in healthy elderly individuals
- Traditionally used in Ayurvedic medicine to relieve feelings of general malaise/general debility In older females
- Traditionally used in Ayurvedic medicine to longevity tonic
- Traditionally used in Ayurvedic medicine to helps enhance/promote general health and wellbeing
- Traditionally used in Western herbal medicine to antispasmodic/spasmolytic
- Traditionally used in Western herbal medicine to adaptogen/Help body adapt to stress
- Traditionally used in Western herbal medicine to relieve irritability
- Traditionally used in Ayurvedic medicine to calms the mind
- Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy
- Traditionally used in Ayurvedic medicine to soothe/calm nerves
- Traditionally used in Western herbal medicine to soothe/calm nerves
- 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 Ayurvedic medicine to maintain/support cognitive function/mental function
- Traditionally used in Ayurvedic medicine to maintain/support memory/mental recall
- Traditionally used in Ayurvedic medicine to nerve tonic
- Traditionally used in Ayurvedic medicine to calmative/nervous system relaxant
- Traditionally used in Ayurvedic medicine to nervine/support nervous system
- Traditionally used in Western herbal medicine to soporific/induces sleep
- Traditionally used in Ayurvedic medicine to soporific/induces sleep
- Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve sleeplessness

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Traditionally used in Western herbal medicine to decrease/reduce/relieve disturbed/restless sleep
 Traditionally used in Western herbal medicine to 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 not imply or refer to serious musculoskeletal or neurological conditions.
 If Ayurvedic terminology is used on medicine label, label statement: Talk to a Ayurvedic practitioner/health professional if you are unsure if this medicine is right for you.
 Product presentation must not imply or refer to chronic fatigue syndrome.

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
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Components

1 . Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral

Visual Identification

Active Ingredients

Lavender Oil	20 mg
Passiflora incarnata herb flowering and fruiting Extract dry concentrate	150 mg
Equivalent: Passiflora incarnata (Dry)	750 mg
Withania somnifera root Extract dry concentrate	150 mg
Equivalent: Withania somnifera (Dry)	1.5 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
 colloidal anhydrous silica
 crospovidone
 hypromellose
 magnesium stearate
 maltodextrin
 microcrystalline cellulose
 silicon dioxide

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