



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	376177	Thompson's Ashwagandha Complex Stress + Focus
<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>	12/10/2021	
<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 Ashwagandha Complex Stress + Focus**

Product Type	Single Medicine Product	Effective Date	12/10/2021
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**Permitted Indications**

- Traditionally used in Ayurvedic medicine to medhya/brain tonic/improve memory and cognition
- 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 enhance/promote energy levels
- 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 healthy elderly individuals
- 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 maintain/support general health and wellbeing
- Traditionally used in Ayurvedic medicine to cardi tonic/strengthen heart
- Traditionally used in Western herbal medicine to adaptogen/Help body adapt to stress
- Traditionally used in Ayurvedic medicine to calms the mind
- Traditionally used in Ayurvedic medicine to soothe/calm nerves
- Traditionally used in Ayurvedic medicine to enhance/improve/promote learning ability/function
- Traditionally used in Ayurvedic medicine to enhance/improve/promote/increase memory/recall
- Traditionally used in Ayurvedic medicine to brain tonic/Enhance brain health
- 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

**Indication Requirements**

- Product presentation must not imply or refer to chronic fatigue syndrome.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.

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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.

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

Product presentation must not imply or refer to serious cardiovascular conditions.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

No Warnings included on Record

#### 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

<b>Bacopa monnieri whole plant Extract dry concentrate</b>	<b>150 mg</b>
Equivalent: Bacopa monnieri (Dry)	3000 mg
<b>Withania somnifera root Extract dry concentrate</b>	<b>150 mg</b>
Equivalent: Withania somnifera (Dry)	1.5 g

#### Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

crospovidone

hypromellose

magnesium stearate

microcrystalline cellulose

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