



**Australian Government**  
**Department of Health**  
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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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 males  
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 relieve feelings of general malaise/general debility In older females  
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 longevity tonic  
Traditionally used in Ayurvedic medicine to maintain/support general health and wellbeing  
Traditionally used in Ayurvedic medicine to cardiotonic/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 serious cardiovascular conditions.  
Product presentation must not imply or refer to mental illnesses, disorders or conditions.



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

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**

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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