



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

## Public Summary

<b>Summary for ARTG Entry:</b>	396775	Mild Anxiety + Stress
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	JSHealth Vitamins Pty Ltd	
<b>Postal Address</b>	31 Knox Street, Double Bay, Sydney, NSW, 2028 Australia	
<b>ARTG Start Date</b>	30/09/2022	
<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 . Mild Anxiety + Stress

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	30/09/2022
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### Permitted Indications

Antioxidant/Reduce free radicals formed in the body  
Traditionally used in Ayurvedic medicine to rasayan/rejuvenative tonic  
Traditionally used in Ayurvedic medicine to relieve feelings of general malaise/general debility  
Maintain/support energy production  
Traditionally used in Ayurvedic medicine to rejuvenating tonic  
Maintain/support immune system health  
Traditionally used in Ayurvedic medicine to adaptogen/Help body adapt to stress  
Traditionally used in Western herbal medicine to relieve irritability  
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 Western herbal medicine to helps reduce occurrence of symptoms of mild anxiety  
Maintain/support cognitive function/mental function  
Maintain/support brain function  
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 only refer to mild anxiety.  
Product presentation must not imply or refer to mental illnesses, disorders or 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.  
If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.  
Product presentation must not imply or refer to serious immunological diseases.



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**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**

ascorbic acid	25 mg
calcium pantothenate	5.46 mg
Equivalent: pantothenic acid	5 mg
choline bitartrate	75 mg
inositol	150 mg
magnesium glycinate dihydrate	215.52 mg
Equivalent: magnesium	25 mg
Matricaria chamomilla flower Extract dry concentrate	28 mg
Equivalent: Matricaria chamomilla (Dry)	224 mg
Melissa officinalis leaf Extract dry concentrate	285.72 mg
Equivalent: Melissa officinalis (Dry)	1 g
Passiflora incarnata flower Extract dry concentrate	52.5 mg
Equivalent: Passiflora incarnata (Dry)	525 mg
Rehmannia glutinosa root Extract dry concentrate	50 mg
Equivalent: Rehmannia glutinosa (Dry)	500 mg
Withania somnifera root Extract dry concentrate	75 mg
Equivalent: Withania somnifera (Dry)	1.5 g

**Other Ingredients (Excipients)**

calcium hydrogen phosphate dihydrate  
Carnauba Wax  
colloidal anhydrous silica  
croscarmellose sodium  
crospovidone  
hypromellose  
iron oxide yellow  
macrogol 400  
magnesium stearate  
microcrystalline cellulose  
povidone  
tapioca starch



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