



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	322172	Anxiety + Stress
ARTG entry for	Medicine Listed	
Sponsor	JSHealth Vitamins Pty Ltd	
Postal Address	17 Kimberley Street, Vaucluse, NSW, 2030 Australia	
ARTG Start Date	22/08/2019	
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . Anxiety + Stress

Product Type	Single Medicine Product	Effective Date	21/10/2019
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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

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.

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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 immunological diseases.

Product presentation must only refer to mild anxiety.

Product presentation must not imply or refer to chronic fatigue syndrome.

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.

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

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magnesium stearate
microcrystalline cellulose
povidone
tapioca starch

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