



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

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|--------------------------------|--|----------------|
| Summary for ARTG Entry: | 354154 | STRESS SUPPORT |
| ARTG entry for | Medicine Listed | |
| Sponsor | Melrose Laboratories Pty Ltd | |
| Postal Address | 16-18 Lionel Rd, Mt Waverley, VIC, 3149 Australia | |
| ARTG Start Date | 3/02/2021 | |
| 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.

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 . STRESS SUPPORT

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 22/02/2021 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Traditionally used in Ayurvedic medicine to medhya/brain tonic/improve memory and cognition
- Traditionally used in Ayurvedic medicine to rasayan/rejuvenative tonic
- Maintain/support energy levels
- Traditionally used in Ayurvedic medicine to relieve feelings of general malaise/general debility
- Maintain/support energy production
- Maintain/support general health and wellbeing
- Decrease/reduce/relieve mild rheumatic aches and pains
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Traditionally used in Western herbal medicine to adaptogen/Help body adapt to stress
- Support healthy stress response in the body
- Decrease/reduce/relieve symptoms of stress
- Maintain/support mental endurance/stamina
- Traditionally used in Western herbal medicine to maintain/support cognitive function/mental function
- Maintain/support nerve conduction
- Aid/assist/helps synthesis of neurotransmitters
- Aid/assist/helps synthesis of neurotransmitters
- Traditionally used in Ayurvedic medicine to nervine/support nervous system
- Maintain/support nervous system function
- Support healthy emotional/mood balance
- Decrease/reduce/relieve sleeplessness when dietary intake is inadequate
- Maintain/support healthy sleeping patterns when dietary intake is inadequate
- Traditionally used in Ayurvedic medicine to maintain/support healthy sleeping patterns

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Maintain/support skin health

Indication Requirements

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

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.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

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

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

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.

Product presentation must only refer to mild rheumatic aches/pains.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

| | |
|---|-------------------|
| ascorbic acid | 250 mg/g |
| magnesium glycinate | 75 mg/g |
| Equivalent: magnesium | 7.5 mg/g |
| Ocimum tenuiflorum whole plant Extract dry concentrate | 100 mg/g |
| Equivalent: Ocimum tenuiflorum (Dry) | 1000 mg/g |
| pyridoxine hydrochloride | 7.5 mg/g |
| Equivalent: pyridoxine | 6.17 mg/g |
| Rhodiola rosea root Extract dry concentrate | 50 mg/g |
| Equivalent: Rhodiola rosea (Dry) | 500 mg/g |
| Withania somnifera root Extract dry concentrate | 31.25 mg/g |
| Equivalent: Withania somnifera (Dry) | 625 mg/g |
| zinc citrate | 5 mg/g |
| Equivalent: zinc | 1.7 mg/g |

Other Ingredients (Excipients)

citric acid

colloidal anhydrous silica

Flavour

glucose monohydrate

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thaumatin

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