



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

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|--------------------------------|--|----------------------------------|
| Summary for ARTG Entry: | 352194 | AM + Stress + Energy + Adaptogen |
| ARTG entry for | Medicine Listed | |
| Sponsor | JSHealth Vitamins Pty Ltd | |
| Postal Address | 14/409 New South Head Road, Double Bay, Sydney, NSW, 2028 Australia | |
| ARTG Start Date | 23/12/2020 | |
| 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 . AM + Stress + Energy + Adaptogen

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 17/02/2021 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support collagen formation
- Maintain/support energy levels
- Helps convert (state food) into energy
- Maintain/support energy production
- Maintain/support physical endurance/capacity/stamina
- Relieve weariness/tiredness/fatigue/feeling of weakness when dietary intake is inadequate
- Traditionally used in Western herbal medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Maintain/support healthy eye function
- Maintain/support eye health
- Maintain/support healthy eyesight/vision
- Maintain/support body mucous membrane health
- Maintain/support general health and wellbeing
- Maintain/support hair health
- Maintain/support healthy teeth
- Decrease/reduce nail brittleness/splitting/chipping in females
- Maintain/support nail health/strength/thickness
- Enhance/improve/promote/increase nail health/strength/thickness in females
- Maintain/support connective tissue health
- Aid/assist/helps connective tissue production/formation
- Maintain/support bone health
- Aid/assist healthy red blood cell production
- Maintain/support blood health
- Helps maintain/support haemoglobin formation/synthesis
- Maintain/support blood capillary health
- Maintain/support blood vessel health

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Maintain/support healthy thyroid gland function in healthy adults
Maintain/support healthy thyroid hormones in healthy adults
Aid/assist thyroid hormone production in healthy adults
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
Maintain/support immune system health
Maintain/support healthy immune system function
Aid/assist/helps protein synthesis in the body
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)
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Traditionally used in Western herbal medicine to adaptogen/Help body adapt to stress
Aids/assists the body to cope with environmental stress
Support healthy stress response in the body
Maintain/support cognitive function/mental function in healthy adults
Traditionally used in Western herbal medicine to nerve tonic
Maintain/support nerve conduction
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system health
Maintain/support nervous system function
Maintain/support female reproductive system health
Maintain/support preconception health in healthy females
Maintain/support preconception health in healthy males
Maintain/support reproductive system health in males
Maintain/support healthy reproductive hormones
Maintain/support sperm health in healthy males
Maintain/support sperm motility in healthy males
Maintain/support sperm production in healthy males
Maintain/support testosterone level
Maintain/support skin health
Maintain/support skin integrity/structure
Maintain/support skin regeneration
Maintain/support wound healing

Indication Requirements

Product presentation must not imply or refer to infertility.
Product presentation must not imply or refer to chronic fatigue syndrome.
Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.
Product presentation must not imply or refer to serious cardiovascular conditions.
Product presentation must not imply or refer to any thyroid related diseases.
Product presentation must not imply or refer to mental illnesses, disorders or conditions.
Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.
If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.
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.
Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to serious immunological diseases.
Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
Product presentation must not imply or refer to gastro oesophageal reflux disease.
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 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 hormone imbalances.

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Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

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 | 150 mg |
| Biotin | 2.5 mg |
| calcium folinate | 271 microgram |
| Equivalent: folic acid | 250 microgram |
| calcium pantothenate | 54.59 mg |
| Equivalent: pantothenic acid | 50 mg |
| mecobalamin (co-methylcobalamin) | 100 microgram |
| Panax quinquefolius root Extract dry concentrate | 275 mg |
| Equivalent: Panax quinquefolius (Dry) | 2.75 g |
| pyridoxine hydrochloride | 12.15 mg |
| Equivalent: pyridoxine | 10 mg |
| Rehmannia glutinosa root Extract dry concentrate | 40 mg |
| Equivalent: Rehmannia glutinosa (Dry) | 400 mg |
| Rhodiola rosea root Extract dry concentrate | 150 mg |
| Equivalent: Rhodiola rosea (Dry) | 1.2 g |
| selenomethionine | 186 microgram |
| Equivalent: selenium | 75 microgram |
| tyrosine | 75 mg |
| zinc amino acid chelate | 40 mg |
| Equivalent: zinc | 8 mg |

Other Ingredients (Excipients)

- calcium hydrogen phosphate dihydrate
- Carnauba Wax
- colloidal anhydrous silica
- croscarmellose sodium
- crospovidone
- hypromellose
- iron oxide yellow
- macrogol 400
- macrogol 6000
- macrogol 8000
- magnesium stearate

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microcrystalline cellulose

povidone

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