



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

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|--------------------------------|--|---------|
| Summary for ARTG Entry: | 329143 | AM + PM |
| ARTG entry for | Medicine Listed | |
| Sponsor | JSHealth Vitamins Pty Ltd | |
| Postal Address | 31 Knox Street, Double Bay, Sydney, NSW, 2028 Australia | |
| ARTG Start Date | 24/01/2020 | |
| 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 + PM

| | | | |
|---------------------|----------------|-----------------------|------------|
| Product Type | Composite Pack | Effective Date | 31/01/2023 |
|---------------------|----------------|-----------------------|------------|

Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Maintain/support collagen formation
Traditionally used in Chinese medicine to engender Fluid
Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish Qi
Traditionally used in Chinese medicine to nourish yin/yin element/stratum
Maintain/support energy levels
Helps convert (state food) into energy
Maintain/support heat/energy production/thermogenesis
Traditionally used in Western herbal medicine to relieve weariness/tiredness/fatigue/feeling of weakness
Traditionally used in Chinese 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 electrolyte balance
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 healthy females
Maintain/support nail health/strength/thickness
Enhance/improve/promote/increase nail health/strength/thickness in healthy 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

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Helps maintain/support haemoglobin formation/synthesis
Maintain/support cardiovascular system health
Maintain/support healthy cardiovascular system function
Maintain/support heart health
Maintain/support blood capillary health
Maintain/support blood vessel health
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 flatulence/carminative
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
Maintain/support muscle function
Maintain/support healthy neuromuscular 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
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
Aids/assists the body to cope with environmental stress
Support healthy stress response in the body
Calms the mind
Soothe/calm nerves
Traditionally used in Western herbal medicine to decrease/reduce/relieve nervous tension/unrest
Decrease/reduce/relieve symptoms of mild anxiety
Maintain/support cognitive function/mental function in healthy adults
Traditionally used in Western herbal medicine to decrease/reduce/relieve headache symptoms
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 health
Traditionally used in Western herbal medicine to nervine/support nervous system
Maintain/support nervous system function
Traditionally used in Western herbal medicine to soporific/induces sleep
Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness
Decrease/reduce/relieve disturbed/restless sleep
Maintain/support female reproductive system health
Maintain/support reproductive system health in healthy 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

Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to serious cardiovascular conditions.
Product presentation must not imply or refer to gastro oesophageal reflux disease.



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Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Product presentation must not imply or refer to hormone imbalances.

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

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 musculoskeletal or neurological conditions.

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 serious immunological diseases.

Product presentation must not imply or refer to infertility.

Product presentation must not imply or refer to any thyroid related 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.

If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

Product presentation must only refer to mild anxiety.

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 . Sleep + Calm

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

| | |
|--------------------------------------|------------------|
| Lavender Oil | 81 mg |
| magnesium amino acid chelate | 100 mg |
| Equivalent: magnesium | 20 mg |
| magnesium citrate | 500 mg |
| Equivalent: magnesium | 81 mg |
| magnesium glycinate dihydrate | 431.03 mg |
| Equivalent: magnesium | 50 mg |

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
chlorophyllin-copper complex
colloidal anhydrous silica
croscarmellose sodium
crospovidone
hypromellose
macrogol 400
magnesium stearate

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microcrystalline cellulose

povidone

2 . Stress + Energy

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

| | |
|--|----------|
| ascorbic acid | 150 mg |
| Biotin | 2.5 mg |
| calcium folinate | .27 mg |
| Equivalent: folic acid | .25 mg |
| calcium pantothenate | 54.59 mg |
| Equivalent: pantothenic acid | 50 mg |
| Equivalent: calcium | 4.59 mg |
| mecobalamin (co-methylcobalamin) | .1 mg |
| Panax quinquefolius root Extract dry concentrate | 350 mg |
| Equivalent: Panax quinquefolius (Dry) | 3.5 g |
| pyridoxine hydrochloride | 25 mg |
| Equivalent: pyridoxine | 20.57 mg |
| Rehmannia glutinosa root Extract dry concentrate | 40 mg |
| Equivalent: Rehmannia glutinosa (Dry) | 400 mg |
| selenomethionine | .186 mg |
| Equivalent: selenium | .075 mg |
| tyrosine | 75 mg |
| zinc amino acid chelate | 75 mg |
| Equivalent: zinc | 15 mg |

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
colloidal anhydrous silica
croscarmellose sodium
crospovidone
hypromellose
iron oxide yellow
macrogol 400
magnesium stearate
maltodextrin
microcrystalline cellulose
Peppermint Oil
povidone
titanium dioxide

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