



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	352194	AM+ Stress + Energy Levels
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 Levels

Product Type	Single Medicine Product	Effective Date	31/01/2023
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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 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 mental illnesses, disorders or conditions.

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 chronic fatigue syndrome.

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 any thyroid related diseases.

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).

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 hormone imbalances.

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 infertility.

Product presentation must not imply or refer to serious immunological diseases.

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 gastro oesophageal reflux disease.

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

Standard Indications

No Standard Indications included on Record

Specific Indications



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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
microcrystalline cellulose
povidone



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