



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	329143	AM + PM
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	JSHealth Vitamins Pty Ltd	
<b>Postal Address</b>	17 Kimberley Street, Vaucluse, NSW, 2030 Australia	
<b>ARTG Start Date</b>	24/01/2020	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 . AM + PM

<b>Product Type</b>	Composite Pack	<b>Effective Date</b>	24/01/2020
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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  
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

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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  
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 preconception health in healthy females  
Maintain/support preconception health in healthy males  
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

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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.

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 serious cardiovascular conditions.

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 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.

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

Product presentation must not imply or refer to infertility.

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 any thyroid related diseases.

Product presentation must not imply or refer to gastro oesophageal reflux disease.

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 only refer to mild anxiety.

If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

**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**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Stress + Energy**

<b>Dosage Form</b>	Tablet, film coated
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

<b>ascorbic acid</b>	<b>150 mg</b>
<b>Biotin</b>	<b>2.5 mg</b>
<b>calcium folinate</b>	<b>.27 mg</b>
Equivalent: folic acid	.25 mg
<b>calcium pantothenate</b>	<b>54.59 mg</b>
Equivalent: pantothenic acid	50 mg
Equivalent: calcium	4.59 mg

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<b>mecobalamin (co-methylcobalamin)</b>	<b>.1 mg</b>
<b>Panax quinquefolius root Extract dry concentrate</b>	<b>350 mg</b>
Equivalent: Panax quinquefolius (Dry)	3.5 g
<b>pyridoxine hydrochloride</b>	<b>25 mg</b>
Equivalent: pyridoxine	20.57 mg
<b>Rehmannia glutinosa root Extract dry concentrate</b>	<b>40 mg</b>
Equivalent: Rehmannia glutinosa (Dry)	400 mg
<b>selenomethionine</b>	<b>.186 mg</b>
Equivalent: selenium	.075 mg
<b>tyrosine</b>	<b>75 mg</b>
<b>zinc amino acid chelate</b>	<b>75 mg</b>
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

**2 . Sleep + Calm**

**Dosage Form**                      Tablet, film coated  
**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

<b>Lavender Oil</b>	<b>81 mg</b>
<b>magnesium amino acid chelate</b>	<b>100 mg</b>
Equivalent: magnesium	20 mg
<b>magnesium citrate</b>	<b>500 mg</b>
Equivalent: magnesium	81 mg
<b>magnesium glycinate dihydrate</b>	<b>431.03 mg</b>
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
- microcrystalline cellulose

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povidone

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