



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	373034	Thyroid +
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	18/08/2021	
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 . Thyroid +

Product Type	Single Medicine Product	Effective Date	25/08/2021
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support collagen formation
- Traditionally used in Chinese medicine to invigorate/activate Blood
- Traditionally used in Chinese medicine to eliminate/reduce/remove/resolve/dissipate blood-stasis
- Traditionally used in Chinese medicine to increase/augment/generate/promote/strengthen qi
- Traditionally used in Chinese medicine to dispel/expel/extinguish/disperse/clear wind-dampness
- Maintain/support energy levels
- Maintain/support body metabolism/metabolic rate
- Maintain/support energy production
- Maintain/support heat/energy production/thermogenesis
- Maintain/support healthy eye function
- Maintain/support eye health
- Traditionally used in Chinese medicine to maintain/support general health and wellbeing
- Maintain/support general health and wellbeing
- Maintain/support hair growth
- Maintain/support hair health
- Maintain/support healthy teeth
- Aid/assist nail growth
- Maintain/support nail health/strength/thickness
- Maintain/support connective tissue health
- Aid/assist/helps connective tissue production/formation
- Maintain/support healthy body tissues
- Maintain/support bone health
- Aid/assist healthy red blood cell production
- Maintain/support red blood cell health
- Maintain/support blood capillary health
- Maintain/support blood vessel health

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Maintain/support healthy thyroid gland function
Maintain/support healthy thyroid hormones
Maintain/support thyroid gland health
Aid/assist thyroid hormone production
Maintain/support liver health
Maintain/support immune system health
Maintain/support healthy immune system function
Aid/assist/helps glucose/sugar/carbohydrate metabolism
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)
Maintain/support cognitive function/mental function
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
Traditionally used in Chinese medicine to improve menstrual flow
Traditionally used in Chinese medicine to decrease/reduce/relieve menstruation pain/dysmenorrhoea
Maintain/support preconception health in healthy males
Maintain/support preconception health in healthy females
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 skin health
Maintain/support skin integrity/structure
Maintain/support skin regeneration

Indication Requirements

Product presentation must not imply or refer to serious cardiovascular conditions.

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.

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 vision correction, faults or serious eye disease e.g. macular degeneration.

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 any thyroid related diseases.

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 circulatory disorders/diseases/conditions e.g. thrombosis.

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).

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 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 liver disease, such as cirrhosis, hepatitis.

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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

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.



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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

Ascophyllum nodosum Blade and Stem Powder	41.6 mg
ascorbic acid	50 mg
chromic chloride hexahydrate	512.3 microgram
Equivalent: chromium	100 microgram
Curcuma longa rhizome Extract dry concentrate	200 mg
Equivalent: Curcuma longa (Dry)	2 g
mecobalamin (co-methylcobalamin)	25 microgram
nicotinamide	10 mg
Plectranthus barbatus root Extract dry concentrate	17.65 mg
Equivalent: Plectranthus barbatus (Dry)	1.2 g
pyridoxal 5-phosphate	7.81 mg
Equivalent: pyridoxine	5 mg
Rehmannia glutinosa root Extract dry concentrate	40 mg
Equivalent: Rehmannia glutinosa (Dry)	400 mg
riboflavin	5 mg
selenomethionine	93.1 microgram
Equivalent: selenium	37.5 microgram
tyrosine	250 mg
zinc citrate dihydrate	18.67 mg
Equivalent: zinc	6 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
 Carnuba Wax
 colloidal anhydrous silica
 croscarmellose sodium
 crospovidone
 hypromellose
 macrogol 400
 magnesium stearate
 maltodextrin
 microcrystalline cellulose
 Peppermint Oil

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povidone

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