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#### **Australian Government**

# **Department of Health and Aged Care**

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 31/01/2023

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

Product presentation must not imply or refer to infertility.

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

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

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.

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

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.

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).

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If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased

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

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

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

Product presentation must not imply or refer to hormone imbalances.

## 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** 

Ascophyllum nodosum Blade and Stem Powder

ascorbic acid

chromic chloride hexahydrate

Equivalent: chromium

Curcuma longa rhizome Extract dry concentrate

Equivalent: Curcuma longa (Dry)

mecobalamin (co-methylcobalamin)

nicotinamide

Plectranthus barbatus root Extract dry concentrate

Equivalent: Plectranthus barbatus (Dry)

pyridoxal 5-phosphate

Equivalent: pyridoxine

Rehmannia glutinosa root Extract dry concentrate

Equivalent: Rehmannia glutinosa (Dry)

riboflavin

selenomethionine

Equivalent: selenium

tyrosine

zinc citrate dihydrate

Equivalent: zinc

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

Carnauba Wax

colloidal anhydrous silica

croscarmellose sodium

crospovidone

hypromellose

macrogol 400

magnesium stearate

maltodextrin

microcrystalline cellulose

Peppermint Oil

povidone

41.6 mg

50 mg

**512.3 microgram** 100 microgram

200 mg

2 g

25 microgram

10 mg

**17.65 mg** 1.2 g

7.81 mg

5 mg **40 mg** 

400 mg

5 mg

93.1 microgram

37.5 microgram

250 mg

18.67 mg

6 mg



# Department of Health and Aged Care

Therapeutic Goods Administration

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