

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 373907 Libido +

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 31/08/2021

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 . Libido +

Product Type Single Medicine Product Effective Date 6/01/2023

Permitted Indications

Maintain/support energy levels

Helps convert (state food) into energy

Maintain/support energy production

Traditionally used in Western herbal medicine to relieve weariness/tiredness/fatigue/feeling of weakness

Maintain/support general health and wellbeing

Maintain/support bone health

Helps maintain/support healthy blood sugar/glucose

Maintain/support cardiovascular system health

Maintain/support healthy cardiovascular system function

Maintain/support heart health

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia

Decrease/reduce/relieve muscle cramps

Decrease/reduce/relieve muscle cramps when dietary intake is inadequate

Maintain/support healthy muscle contraction function

Maintain/support muscle function

Maintain/support healthy neuromuscular system/function

Maintain/support muscle relaxation

Aid/assist/helps glucose/sugar/carbohydrate metabolism

Aid/assist/helps protein synthesis in the body

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

Traditionally used in Western herbal medicine to nerve tonic

Maintain/support nervous system health

Maintain/support nervous system function

Traditionally used in Ayurvedic medicine to maintain/support healthy libido

Traditionally used in Ayurvedic medicine to maintain/support healthy sexual function

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This is not an ARTG Certificate document.



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Maintain/support skin health

Indication Requirements

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 gastro oesophageal reflux disease.

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.

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

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 lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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

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

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

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

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).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

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

| Ginkgo biloba leaf Extract dry concentrate | 100 mg |
|---|-----------|
| Equivalent: Ginkgo biloba (Dry) | 5 g |
| magnesium citrate | 649.75 mg |
| Equivalent: magnesium | 105 mg |
| nicotinamide | 20 mg |
| nicotinic acid | 5 mg |
| Panax quinquefolius root Extract dry concentrate | 100 mg |
| Equivalent: Panax quinquefolius (Dry) | 1 g |
| Rhodiola rosea root Extract dry concentrate | |
| Equivalent: Rhodiola rosea (Dry) | 600 mg |
| Tribulus terrestris fruit Extract dry concentrate | 200 mg |
| Equivalent: Tribulus terrestris (Dry) | 10 g |
| | |

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

Carnauba Wax

colloidal anhydrous silica

croscarmellose sodium

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Produced at 19.01.2023 at 04:07:19 AEDT

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crospovidone
hypromellose
macrogol 400
magnesium stearate
maltodextrin
microcrystalline cellulose
povidone

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