



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

| | | |
|--------------------------------|---|---------------|
| Summary for ARTG Entry: | 338773 | Hair + Energy |
| ARTG entry for | Medicine Listed | |
| Sponsor | JSHealth Vitamins Pty Ltd | |
| Postal Address | 17 Kimberley Street, Vaucluse, NSW, 2030 Australia | |
| ARTG Start Date | 2/07/2020 | |
| 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 . Hair + Energy

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 21/03/2022 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Maintain/support energy levels
Maintain/support body metabolism/metabolic rate
Maintain/support healthy growth and development
Maintain/support general health and wellbeing
Maintain/support hair growth when dietary intake is inadequate
Maintain/support hair health when dietary intake is inadequate
Maintain/support hair strength/thickness in females
Maintain/support nail health/strength/thickness in females
Maintain/support connective tissue health
Aid/assist/helps connective tissue production/formation
Maintain/support healthy thyroid gland function
Maintain/support healthy thyroid hormones
Maintain/support thyroid gland health
Aid/assist thyroid hormone production
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support immune system to fight illness
Aid/assist/helps glucose/sugar/carbohydrate metabolism
Aid/assist/helps protein synthesis in the body
Maintain/support cognitive function/mental function
Maintain/support brain function
Maintain/support nervous system health
Maintain/support healthy reproductive hormones
Maintain/support sperm health
Maintain/support skin health

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Maintain/support wound healing

Indication Requirements

Product presentation must not imply or refer to infertility.
Product presentation must not imply or refer to serious immunological diseases.
Product presentation must not imply or refer to mental illnesses, disorders or conditions.

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

Product presentation must not imply or refer to any thyroid related diseases.
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 hormone imbalances.
Product presentation must not imply or refer to chronic fatigue syndrome.

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.

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 | Capsule, hard |
| Route of Administration | Oral |

Visual Identification

Active Ingredients

| | |
|--|---------------|
| Ascophyllum nodosum Blade and Stem Powder | 294 mg |
| Fucus vesiculosus whole plant Extract dry concentrate | 50 mg |
| Equivalent: Fucus vesiculosus (Dry) | 1 g |
| zinc amino acid chelate | 50 mg |
| Equivalent: zinc | 10 mg |

Other Ingredients (Excipients)

colloidal anhydrous silica
hypromellose
magnesium stearate
microcrystalline cellulose
purified water

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