# **Australian Government**

## **Department of Health**

# Therapeutic Goods Administration

#### **Public Summary**

Summary for ARTG Entry: 377597 Hair + Energy

ARTG entry for Medicine Listed

Sponsor JSHealth Vitamins Pty Ltd

Postal Address 31 Knox Street, Double Bay, Sydney, NSW, 2028

Australia

ARTG Start Date 8/11/2021
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 . Hair + Energy

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

# Permitted Indications

Maintain/support energy levels

Maintain/support body metabolism/metabolic rate

Maintain/support energy production

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 healthy thyroid gland function

Maintain/support healthy thyroid hormones

Maintain/support thyroid gland health

Aid/assist thyroid hormone production

Maintain/support cognitive function/mental function

Maintain/support brain function

Maintain/support skin health in females

## **Indication Requirements**

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 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 chronic fatigue syndrome.

# **Standard Indications**

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

# Page 1 of 2



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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             | 211.11 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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