Produced at 01.07.2022 at 03:41:48 AEST



Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 351621 Hair + 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 11/12/2020
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 + Libido

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 energy production

Maintain/support general health and wellbeing

Maintain/support hair growth

Maintain/support hair health

Maintain/support hair strength/thickness in females

Maintain/support nail health/strength/thickness

Maintain/support connective tissue health

Aid/assist/helps connective tissue production/formation

Maintain/support healthy blood circulation

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 mental concentration/focus/clarity

Maintain/support cognitive function/mental function

Maintain/support memory/mental recall

Maintain/support general mental wellbeing

Maintain/support brain function

Page 1 of 3

This is not an ARTG Certificate document.



Australian Government

Department of Health

Therapeutic Goods Administration

Maintain/support nervous system health

Maintain/support female reproductive system health

Maintain/support preconception health in healthy males

Maintain/support reproductive system health in males

Maintain/support healthy reproductive hormones

Traditionally used in Ayurvedic medicine to aphrodisiac/Enhance/improve/promote healthy libido

Traditionally used in Ayurvedic medicine to maintain/support healthy libido

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

Maintain/support sperm health

Maintain/support sperm motility in healthy males

Maintain/support sperm production in healthy males

Maintain/support testosterone level

Maintain/support skin health

Maintain/support wound healing

Indication Requirements

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

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

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

If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

Product presentation must not imply or refer to infertility.

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.

 $\label{product} \mbox{Product presentation must not imply or refer to serious cardiovascular conditions.}$

Product presentation must not imply or refer to any thyroid related diseases.

Product presentation must not imply or refer to hormone imbalances.

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.

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

294 mg
50 mg
1 g
120 mg
6 g
200 mg
10 g

Page 2 of 3

Produced at 01.07.2022 at 03:41:48 AEST



Australian Government

Department of Health

Therapeutic Goods Administration

zinc amino acid chelate50 mgEquivalent: zinc10 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

Carnauba Wax

colloidal anhydrous silica

croscarmellose sodium

crospovidone

hypromellose

Lavender Oil

macrogol 400

magnesium stearate

maltodextrin

microcrystalline cellulose

Peppermint Oil

povidone

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at http://www.tga.gov.au/about/website-copyright.htm.