Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 371270 Silica Hair Solution

ARTG entry for Medicine Listed

Sponsor Herbs of Gold Pty Ltd

Postal Address PO Box 3143, KIRRAWEE, NSW, 2232

Australia

ARTG Start Date 19/07/2021

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 . Silica Hair Solution

Product Type Single Medicine Product Effective Date 19/07/2021

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Maintain/support collagen formation

Maintain/support collagen health

Maintain/support general health and wellbeing

Maintain/support hair health

Maintain/support hair strength/thickness

Maintain/support nail health/strength/thickness

Maintain/support connective tissue health

Aid/assist/helps connective tissue production/formation

Maintain/support bone health

Maintain/support bone mass/density/integrity

Help maintain/support bone mineralisation

Maintain/support immune system health

Maintain/support healthy immune system function

Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)

Maintain/support skin health

Maintain/support skin elasticity

Maintain/support skin integrity/structure

Maintain/support wound healing

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 serious immunological diseases.

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

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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Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.

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 Oral Liquid **Route of Administration** Oral

Visual Identification

Active Ingredients

Biotin .3 mg/mL colloidal anhydrous silica 63.05 mg/mL Equivalent: silicon 28 mg/mL

selenomethionine 6.25 microgram/mL Equivalent: selenium 2.5 microgram/mL zinc citrate dihydrate 7.94 mg/mL Equivalent: zinc 2.5 mg/mL

Other Ingredients (Excipients)

citric acid Flavour potassium sorbate purified water Stevia rebaudiana

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