



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	371090	Silica Hair Skin & Nails
ARTG entry for	Medicine Listed	
Sponsor	Herbs of Gold Pty Ltd	
Postal Address	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
ARTG Start Date	15/07/2021	
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 Skin & Nails

Product Type	Single Medicine Product	Effective Date	15/07/2021
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Maintain/support collagen formation
Maintain/support collagen health
Maintain/support healthy eye function
Maintain/support eye health
Maintain/support healthy eyesight/vision
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 blood capillary health
Maintain/support blood vessel health
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support (state vitamin/mineral/nutrient) levels in the body
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 vision correction, faults or serious eye disease e.g. macular degeneration.



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

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 used.

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

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).

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

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.

WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral

Visual Identification

Active Ingredients

ascorbic acid	200 mg
Biotin	2.5 mg
calcium pantothenate	27.29 mg
Equivalent: pantothenic acid	25 mg
colloidal anhydrous silica	193.5 mg
Equivalent: silicon	90 mg
glycine	20 mg
lysine	20 mg
proline	20 mg
retinol acetate	860 microgram
Equivalent: vitamin A	750 RE/microgram
silicon dioxide	269.51 mg
Equivalent: silicon	126 mg
zinc amino acid chelate	100 mg
Equivalent: zinc	20 mg

Other Ingredients (Excipients)

- Acacia
- calcium hydrogen phosphate dihydrate
- Carnauba Wax
- croscarmellose sodium
- crospovidone
- dl-alpha-tocopherol
- hypromellose

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macrogol 400
magnesium stearate
maize starch
maltodextrin
microcrystalline cellulose
povidone
tapioca starch

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