



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	325929	ETHICAL NUTRIENTS HEALTHY HAIR, SKIN & NAILS
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	5/11/2019	
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . ETHICAL NUTRIENTS HEALTHY HAIR, SKIN & NAILS

Product Type	Single Medicine Product	Effective Date	11/03/2020
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body in females
- Maintain/support collagen formation in females
- Maintain/support hair health in females
- Decrease/reduce nail brittleness/splitting/chipping in females
- Maintain/support nail health/strength/thickness in females
- Aid/assist/helps connective tissue production/formation in females
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in females
- Maintain/support skin firmness in females
- Maintain/support skin health in females
- Maintain/support skin elasticity in females
- Maintain/support skin integrity/structure in females
- Maintain/support wound healing in females

Indication Requirements

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).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings



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If symptoms persist consult your healthcare practitioner (or words to that effect).

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

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.

Not to be taken by children under 2 years old (or words to that effect).

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

betacarotene	4.8 mg
Biotin	2.5 mg
borax	26.46 mg
Equivalent: boron	2.99 mg
d-alpha-tocopheryl acid succinate	12.31 mg
Fucus vesiculosus whole plant Extract dry concentrate	200 mg
Equivalent: Fucus vesiculosus (Dry)	1 g
lycopene	6 mg
manganese amino acid chelate	93.75 mg
Equivalent: manganese	15 mg
selenomethionine	188 microgram
Equivalent: selenium	75 microgram
silicon dioxide	106.96 mg
Equivalent: silicon	50 mg
zinc amino acid chelate	75 mg
Equivalent: zinc	15 mg

Other Ingredients (Excipients)

- calcium hydrogen phosphate dihydrate
- calcium hydrogen phosphate
- citric acid
- croscarmellose sodium
- dl-alpha-tocopherol
- hypromellose
- liquid glucose
- macrogol 400
- magnesium stearate
- maize starch
- maltodextrin
- microcrystalline cellulose
- potable water
- sodium ascorbate
- sodium starch glycollate type A
- starch sodium octenyl succinate

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