



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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|--------------------------------|--|-------------------------------|
| Summary for ARTG Entry: | 333379 | Thompson's Skin, Hair & Nails |
| ARTG entry for | Medicine Listed | |
| Sponsor | Integria Healthcare Australia Pty Ltd | |
| Postal Address | PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia | |
| ARTG Start Date | 5/04/2020 11:00:00 PM | |
| 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 . Thompson's Skin, Hair & Nails

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 28/03/2022 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Maintain/support collagen formation
Maintain/support collagen health
Maintain/support general health and wellbeing
Maintain/support hair health
Decrease/reduce nail brittleness/splitting/chipping
Aid/assist/helps connective tissue production/formation
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Maintain/support (state vitamin/mineral) within normal range
Maintain/support skin health
Maintain/support skin integrity/structure
Maintain/support wound healing
Maintain/support skin repair/healing/regeneration

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).

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Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings



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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.

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

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

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.

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.

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form Capsule, soft

Route of Administration Oral

Visual Identification

Active Ingredients

| | |
|--|----------------------|
| Biotin | 1.25 mg |
| colecalfiferol | 10 microgram |
| colloidal anhydrous silica | 30 mg |
| Equivalent: silicon | 14.03 mg |
| concentrated fish Omega-3 triglycerides | 60 mg |
| Equivalent: docosahexaenoic acid | 12 mg |
| Equivalent: eicosapentaenoic acid | 18 mg |
| d-alpha-tocopherol | 20.12 mg |
| Equivalent: d-alpha-tocopherol | 30 IU |
| demineralised fish proteoglycan extract | 125 mg |
| Evening Primrose Oil | 200 mg |
| pyridoxine hydrochloride | 10 mg |
| Equivalent: pyridoxine | 8.23 mg |
| retinol palmitate | 1.3744 mg |
| Equivalent: vitamin A | .7497 mg |
| selenomethionine | 124 microgram |
| Equivalent: selenium | 50 microgram |
| sodium ascorbate | 33.75 mg |
| Equivalent: ascorbic acid | 30 mg |
| zinc amino acid chelate | 37.5 mg |
| Equivalent: zinc | 7.5 mg |

Other Ingredients (Excipients)

- calcium hydrogen phosphate dihydrate
- dl-alpha-tocopherol
- Gelatin
- glycerol
- hydrogenated vegetable oil
- iron oxide black
- iron oxide red
- iron oxide yellow
- lecithin

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Soya Oil

vegetable oil

yellow beeswax

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