



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	385476	Hair, Skin & Nails
ARTG entry for	Medicine Listed	
Sponsor	Factors Group Australia Pty Ltd	
Postal Address	Unit B 10-16 South Street, Rydalmere, NSW, 2116 Australia	
ARTG Start Date	11/03/2022	
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, Skin & Nails

Product Type	Single Medicine Product	Effective Date	11/03/2022
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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 hair growth
- Maintain/support hair health
- Decrease/reduce nail brittleness/splitting/chipping
- Aid/assist nail growth
- Maintain/support nail health/strength/thickness
- Enhance/improve/promote/increase nail health/strength/thickness
- Maintain/support connective tissue health
- Aid/assist/helps connective tissue production/formation
- Maintain/support body tissue repair/regeneration
- Helps maintain/supports healthy joint cartilage growth/development/production
- Helps maintain/support joint cartilage health
- Maintain/support digestion/assimilation of nutrients
- Aid/assist/helps protein synthesis in the body
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- 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



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Product presentation must not imply or refer to any form of arthritis or osteoarthritis unless qualified as mild.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

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

Adults only.

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin 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 recommended for use by pregnant and lactating women (or words to that effect).

If symptoms persist consult your healthcare practitioner (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

Apium graveolens seed Extract dry concentrate	2.25 mg
Equivalent: Apium graveolens (Dry)	22.5 mg
Apium graveolens herb Extract dry concentrate	160 microgram
Equivalent: Apium graveolens (Fresh)	2.4 mg
Arthrospira platensis	5 mg
Aspalathus linearis leaf Powder	50 mg
Equivalent: Aspalathus linearis (Dry)	50 mg
betacarotene	.6 mg
Beta vulgaris root Powder	2.25 mg
Beta vulgaris root Extract dry concentrate	142 microgram
Equivalent: Beta vulgaris (Fresh)	1.42 mg
Biotin	1.5 mg
Brassica oleracea var. botrytis herb Powder	3.75 mg
Brassica oleracea var. botrytis herb Extract dry concentrate	145 microgram
Equivalent: Brassica oleracea var. botrytis (Fresh)	2.175 mg
Brassica oleracea var. capitata leaf Powder	3.75 mg
Brassica oleracea var. capitata herb Extract dry concentrate	294 microgram
Equivalent: Brassica oleracea var. capitata (Fresh)	13.23 mg
Brassica oleracea var. italica herb Powder	3.75 mg
Brassica oleracea var. viridis herb Powder	2.25 mg
Brassica oleracea var. viridis leaf Extract dry concentrate	26 microgram
Equivalent: Brassica oleracea var. viridis (Fresh)	104 microgram
calcified lithothamnion species	43.1818 mg
Equivalent: magnesium	1 mg

Public Summary



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

calcium ascorbate dihydrate	30.259 mg
Equivalent: ascorbic acid	25 mg
calcium pantothenate	10.87 mg
Equivalent: pantothenic acid	10 mg
Camellia sinensis leaf Extract dry concentrate	5 mg
Equivalent: Camellia sinensis (Dry)	150 mg
Capsicum annuum fruit Extract dry concentrate	208 microgram
Equivalent: Capsicum annuum (Fresh)	4.16 mg
Chlorella vulgaris whole plant Powder	5 mg
choline bitartrate	62.657 mg
Equivalent: choline	25 mg
Citrus sinensis fruit Extract dry concentrate	5 mg
Equivalent: Citrus sinensis (Dry)	1.75 g
colecalfiferol	1.25 microgram
Coriandrum sativum leaf Powder	2.25 mg
Coriandrum sativum leaf Extract dry concentrate	13 microgram
Equivalent: Coriandrum sativum (Fresh)	13 microgram
cupric sulfate	3.9293 mg
Equivalent: copper	1 mg
curcumin	1.5 mg
Cynara scolymus leaf Powder	2.25 mg
Cynara scolymus flower bud Extract dry	1 microgram
Equivalent: Cynara scolymus (Fresh)	599 ng
d-alpha-tocopheryl acid succinate	4.13 mg
Echinacea purpurea herb Extract dry concentrate	70 microgram
Equivalent: Echinacea purpurea (Fresh)	490 microgram
Equisetum arvense herb Extract dry concentrate	2.5 mg
Equivalent: Equisetum arvense (Dry)	6 mg
Eruca sativa leaf Powder	3.75 mg
Euterpe oleracea fruit Juice powder	5 mg
Fragaria vesca fruit Powder	250 microgram
glutathione	25 mg
Hordeum vulgare leaf Powder	2.25 mg
inositol	10 mg
Laminaria digitata whole plant Powder	5 mg
Laminaria japonica whole plant Powder	288 microgram
lycopene	250 microgram
Lycopersicon esculentum fruit Powder	2.25 mg
Lycopersicon esculentum fruit Extract dry concentrate	106 microgram
Equivalent: Lycopersicon esculentum (Fresh)	318 microgram
lysine hydrochloride	3.123 mg
Equivalent: lysine	2.5 mg
magnesium ascorbate	20.317 mg
Equivalent: ascorbic acid	15.238 mg
Equivalent: magnesium	2.134 mg
magnesium citrate	30.94 mg
Equivalent: magnesium	5 mg
magnesium glycinate	30.973 mg
Equivalent: magnesium	4.366 mg
manganese gluconate	3.242 mg
Equivalent: manganese	400 microgram



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

mecobalamin	20 microgram
Medicago sativa herb Extract dry concentrate	1.37 mg
Equivalent: Medicago sativa (Fresh)	34.25 mg
Mentha spicata herb Extract dry concentrate	59 microgram
Equivalent: Mentha spicata (Fresh)	472 microgram
Mentha X piperita herb Extract dry concentrate	165 microgram
Equivalent: Mentha X piperita (Fresh)	1.485 mg
Nasturtium officinale leaf Powder	2.5 mg
Nasturtium officinale leaf Extract dry	7 microgram
Equivalent: Nasturtium officinale (Fresh)	5.6 microgram
nicotinamide	4.9999 mg
Origanum vulgare herb Extract dry concentrate	31 microgram
Equivalent: Origanum vulgare (Fresh)	124 microgram
Petroselinum crispum leaf Powder	2.25 mg
Petroselinum crispum herb Extract dry concentrate	617 microgram
Equivalent: Petroselinum crispum (Fresh)	12.34 mg
Phyllanthus emblica fruit Extract dry concentrate standardised	9.524 mg
Equivalent: Phyllanthus emblica (Dry)	476.2 mg
Punica granatum fruit Powder	250 microgram
pyridoxal 5-phosphate monohydrate	2.191 mg
Equivalent: pyridoxine	1.5 mg
Raphanus sativus root Powder	7.5 mg
Raphanus sativus root Powder	2.25 mg
riboflavin sodium phosphate	1.367 mg
Equivalent: riboflavin	1 mg
Rubus idaeus fruit Powder	250 microgram
Schisandra chinensis fruit Extract dry concentrate	5 mg
Equivalent: Schisandra chinensis (Dry)	100 mg
selenomethionine	46.568 microgram
Equivalent: selenium	18.75 microgram
silicon dioxide	53.533 mg
Equivalent: silicon	25 mg
Taraxacum officinale root Powder	2.25 mg
thiamine hydrochloride	1.271 mg
Equivalent: thiamine	1 mg
Vaccinium macrocarpon fruit Powder	5 mg
Vaccinium macrocarpon fruit Powder	250 microgram
Vaccinium myrtillus fruit Powder	250 microgram
Vitis vinifera seed Extract dry concentrate	21.5 mg
Equivalent: Vitis vinifera (Dry)	795.5 mg
Vitis vinifera seed Extract dry concentrate	2 mg
Equivalent: Vitis vinifera (Dry)	200 mg
zinc citrate dihydrate	11.738 mg
Equivalent: zinc	3.75 mg
Zingiber officinale root Extract dry concentrate	5 mg
Equivalent: Zingiber officinale (Dry)	125 mg

Other Ingredients (Excipients)

Acacia
ascorbic acid
ascorbyl palmitate

Public Summary



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

calcium hydrogen phosphate dihydrate
calcium hydrogen phosphate
chlorophyllin-copper complex
citric acid
croscarmellose sodium
d-alpha-tocopherol
dl-alpha-tocopheryl acetate
fractionated coconut oil
Ghatti Gum
glycerol
hydrolysed maize starch
hypromellose
hypromellose
magnesium stearate
maltodextrin
maltose
microcrystalline cellulose
mixed (high-alpha type) tocopherols concentrate
mono- and di- glycerides
potable water
pregelatinised maize starch
silicon dioxide
stearic acid
sucrose
Sunflower Oil

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Public Summary