



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	118815	Skin Hair & Nails (NZ) soft capsules
ARTG entry for	Medicine Listed (Export Only)	
Sponsor	Sphere Healthcare Pty Ltd	
Postal Address	PO Box 566, MOOREBANK, NSW, 1875 Australia	
ARTG Start Date	27/04/2005	
Product Category	Medicine	
Status	Active	
Approval Area	Export only Medicines	

Conditions

Except where the sponsor has been contracted by an overseas party to manufacturer the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods, and upon the request of the Head, Office of Prescription Medicines Authorisation Branch, Therapeutic Goods Administration, shall produce such evidence to this officer.

The sponsor shall hold stability data to support the claimed shelf life of the listed medicine according to the labelled storage conditions except where: (i) each overseas importer accepts responsibility for holding stability data for this product; (ii) the sponsor has a written agreement to this effect from each overseas importer; and (iii) the sponsor retains copies of all such agreements while the medicine remains listed on the ARTG.

This product must not be supplied for sale in Australia, including supply via duty free outlets.

Products

1 . Skin Hair & Nails (NZ) soft capsules

Product Type	Single Medicine Product	Effective Date	27/04/2005
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Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

Nutritional Supplement

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Medicine Component

Dosage Form	Capsule, soft
Route of Administration	Oral
Visual Identification	Red/Brown oblong shaped soft capsule

Active Ingredients

aminobenzoic acid	5 mg
betacarotene	3 mg
Biotin	75 microgram
calcium ascorbate dihydrate	36.5 mg
Equivalent: ascorbic acid	30 mg
calcium carbonate	100 mg

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Equivalent: calcium	40 mg
d-alpha-tocopherol	20.1 mg
Equivalent: d-alpha-tocopherol	30 IU
dried fish	125 mg
Equisetum arvense herb Extract dry concentrate	50 mg
Equivalent: Equisetum arvense	250 mg
Evening Primrose Oil	200 mg
Equivalent: gamma-linolenic acid	20 mg
natural fish oil	100 mg
Equivalent: eicosapentaenoic acid	18 mg
Equivalent: docosahexaenoic acid	12 mg
pyridoxine hydrochloride	5 mg
Equivalent: pyridoxine	4.11 mg
retinol palmitate	1.3875 mg
selenomethionine	125 microgram
Equivalent: selenium	50 microgram
zinc monomethionine sulfate	37.5 mg
Equivalent: zinc	7.5 mg

Other Ingredients (Excipients)

Arachis Oil
colloidal anhydrous silica
Colour
dl-alpha-tocopherol
Gelatin
glycerol
lecithin
maltodextrin
purified water
Soya Oil
yellow beeswax

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