



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	375215	My Skin
ARTG entry for	Medicine Listed	
Sponsor	Thera Health Pty Ltd	
Postal Address	18/93 Rivergate Place, Murarrie, QLD, 4172 Australia	
ARTG Start Date	24/09/2021	
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 . My Skin

Product Type	Single Medicine Product	Effective Date	24/09/2021
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Relieve minor skin eruptions
Decrease/reduce/relieve pimples
Helps reduce occurrence of pimples
Soothe/relieve skin inflammation
Maintain/support skin health
Maintain/support skin repair/healing/regeneration

Indication Requirements

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

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral

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Visual Identification

Active Ingredients

ascorbic acid	25 mg
betacarotene	.54 mg
Biotin	.25 mg
calcium folinate	.136 mg
Equivalent: folic acid	.125 mg
calcium pantothenate	272.9 mg
Equivalent: pantothenic acid	250 mg
curcumin	10.0008 mg
nicotinamide	50 mg
pyridoxal 5-phosphate monohydrate	7.84 mg
Equivalent: pyridoxine	5 mg
quercetin dihydrate	17 mg
zinc citrate dihydrate	18.7 mg
Equivalent: zinc	6 mg

Other Ingredients (Excipients)

Acacia
colloidal anhydrous silica
hypromellose
lecithin
leucine
maltodextrin
microcrystalline cellulose
Pea Starch
purified water
silicified microcrystalline cellulose
sodium alginate

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