



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	397695	METAGENICS DERMA-CLEAR
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	13/10/2022	
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 . METAGENICS DERMA-CLEAR

Product Type	Single Medicine Product	Effective Date	13/10/2022
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Traditionally used in Western herbal medicine to alterative/blood cleanser/depurative/purifier
Traditionally used in Western herbal medicine to helps maintain/support body's natural channels of elimination
Traditionally used in Western herbal medicine to maintain/support natural body cleansing/detoxification processes
Anti-inflammatory/relieve inflammation
Maintain/support healthy blood circulation
Traditionally used in Western herbal medicine to maintain/support healthy lymphatic system
Traditionally used in Western herbal medicine to relieve minor skin eruptions
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of acne blackheads
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild eczema/dermatitis
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild psoriasis
Maintain/support skin health
Traditionally used in Western herbal medicine to maintain/support skin health

Indication Requirements

Product presentation must only refer to mild psoriasis
Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to drugs/alcohol.
Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
Product presentation must not imply or refer to serious cardiovascular conditions.
Product presentation must only refer to detoxification in relation to natural body processes.
Product presentation must only refer to mild eczema.

Standard Indications

No Standard Indications included on Record

Specific Indications



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No Specific Indications included on Record

Warnings

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

Arctium lappa root Extract dry concentrate	125 mg
Equivalent: Arctium lappa (Dry)	2.5 g
Curcuma longa rhizome Extract dry concentrate	214.29 mg
Equivalent: Curcuma longa (Dry)	5.36 g
Galium aparine herb Extract dry concentrate	250 mg
Equivalent: Galium aparine (Dry)	2.5 g
Taraxacum officinale root Extract dry concentrate	200 mg
Equivalent: Taraxacum officinale (Dry)	2 g
Vitis vinifera seed Extract dry concentrate	75 mg
Equivalent: Vitis vinifera (Fresh)	9 g

Other Ingredients (Excipients)

colloidal anhydrous silica
croscarmellose sodium
glycerol
hypromellose
magnesium stearate
microcrystalline cellulose

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