



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	323888	Dermavital
ARTG entry for	Medicine Listed	
Sponsor	McPherson's Consumer Products Pty Ltd	
Postal Address	Locked Bag 5018, Kingsgrove, NSW, 2208 Australia	
ARTG Start Date	21/09/2019	
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 . Dermavital

Product Type	Single Medicine Product	Effective Date	29/09/2020
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Permitted Indications

- Traditionally used in Western herbal medicine to maintain/support waste elimination via the skin
- Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish Blood
- Traditionally used in Chinese medicine to dispel/expel/disperse/clear external/exogenous wind
- Traditionally used in Chinese medicine to blood tonic/Enhance blood health
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of skin hives
- Traditionally used in Chinese medicine to helps decrease/reduce/relieve symptoms of mild allergies
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of mild eczema/dermatitis
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild psoriasis
 - Linked indication - Decrease/reduce/relieve skin dryness
 - Linked indication - Decrease/reduce/relieve skin scaling/crusty skin
- Traditionally used in Chinese medicine to decrease/reduce/relieve skin dryness
- Traditionally used in Chinese medicine to antipruritic/Relieves itchy skin
- Traditionally used in Chinese medicine to helps enhance/promote skin health
- Traditionally used in Chinese medicine to maintain/support skin health
- Traditionally used in Chinese medicine to helps enhance/promote skin regeneration

Indication Requirements

- If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.
- Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to serious cardiovascular conditions.
- Product presentation must only refer to mild eczema.
- Product presentation must not imply or refer to drugs/alcohol.
- Product presentation must only refer to mild psoriasis
- Product presentation must not imply or refer to serious allergic conditions such as anaphylaxis.
- Product presentation must only refer to detoxification in relation to natural body processes.

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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

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Angelica polymorpha root Extract dry concentrate	75 mg
Equivalent: Angelica polymorpha (Dry)	1.125 g
Arctium lappa root Extract dry concentrate	50 mg
Equivalent: Arctium lappa (Dry)	500 mg
Astragalus membranaceus root Extract dry concentrate	32.5 mg
Equivalent: Astragalus membranaceus (Dry)	325 mg
Glycyrrhiza uralensis root and stolon Extract dry concentrate	30 mg
Equivalent: Glycyrrhiza uralensis (Dry)	150 mg
Paeonia lactiflora root Extract dry concentrate	68.57 mg
Equivalent: Paeonia lactiflora (Dry)	480 mg
Rehmannia glutinosa root Extract dry concentrate	80 mg
Equivalent: Rehmannia glutinosa (Dry)	480 mg
Saposhnikovia divaricata root Extract dry concentrate	100 mg
Equivalent: Saposhnikovia divaricata (Dry)	400 mg
Schizonepeta tenuifolia leaf Extract dry concentrate	150 mg
Equivalent: Schizonepeta tenuifolia (Dry)	750 mg
Tribulus terrestris	32 mg

Other Ingredients (Excipients)

colloidal anhydrous silica
hypromellose
magnesium stearate
maltodextrin
microcrystalline cellulose
purified water

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