



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	362768	An Chuang Ling a.k.a. A C Skin Formula
ARTG entry for	Medicine Listed	
Sponsor	Sun Herbal Pty Ltd	
Postal Address	Unit 5/25 Garema Cct, Kingsgrove, NSW, 2208 Australia	
ARTG Start Date	21/04/2021	
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 . An Chuang Ling a.k.a. A C Skin Formula

Product Type	Single Medicine Product	Effective Date	21/04/2021
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Permitted Indications

- Traditionally used in Chinese medicine to invigorate/activate Blood
- Traditionally used in Chinese medicine to eliminate/reduce/remove/resolve/dissipate blood-stasis
- Traditionally used in Chinese medicine to clear/disperse/expel/dissipate/cool blood-heat
- Traditionally used in Chinese medicine to dispel/expel/extinguish/disperse/clear lung-heat
- Traditionally used in Chinese medicine to clear/expel stomach-heat
- Traditionally used in Chinese medicine to remove Heat toxin

Indication Requirements

- Product presentation must only refer to detoxification in relation to natural body processes.
- Product presentation must not imply or refer to drugs/alcohol.
- 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 serious cardiovascular conditions.
- 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 circulatory disorders/diseases/conditions e.g. thrombosis.
- Product presentation must not imply or refer to disease in any body organ.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

For practitioner dispensing only.

Additional Product information

Pack Size/Poison information

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Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Crataegus pinnatifida fruit Extract dry concentrate	31.7 mg
Equivalent: Crataegus pinnatifida (Dry)	191.16 mg
Eriobotrya japonica leaf Extract dry concentrate	31.7 mg
Equivalent: Eriobotrya japonica (Dry)	191.16 mg
forsythia suspensa fruit Extract dry concentrate	31.7 mg
Equivalent: forsythia suspensa (Dry)	191.16 mg
Gardenia jasminoides fruit Extract dry concentrate	31.7 mg
Equivalent: Gardenia jasminoides (Dry)	191.16 mg
Glycyrrhiza uralensis root Extract dry concentrate	13.19 mg
Equivalent: Glycyrrhiza uralensis (Dry)	79.56 mg
Lonicera japonica flower Extract dry concentrate	31.7 mg
Equivalent: Lonicera japonica (Dry)	191.16 mg
Paeonia obovata root Extract dry concentrate	31.7 mg
Equivalent: Paeonia obovata (Dry)	191.16 mg
Rehmannia glutinosa root Extract dry concentrate	31.7 mg
Equivalent: Rehmannia glutinosa (Dry)	191.16 mg
Salvia miltiorrhiza root Extract dry concentrate	31.7 mg
Equivalent: Salvia miltiorrhiza (Dry)	191.16 mg
Scutellaria baicalensis root Extract dry concentrate	31.7 mg
Equivalent: Scutellaria baicalensis (Dry)	191.16 mg

Other Ingredients (Excipients)

hydrolysed gelatin

soluble maize starch

titanium dioxide

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