

## **Australian Government**

#### **Department of Health**

### Therapeutic Goods Administration

#### **Public Summary**

Summary for ARTG Entry: 342378 Liang Xue Xiao Feng San a.k.a. Clear the 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 26/08/2020
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . Liang Xue Xiao Feng San a.k.a. Clear the Skin Formula

 Product Type
 Single Medicine Product
 Effective Date
 26/08/2020

#### **Permitted Indications**

Traditionally used in Chinese medicine to invigorate/activate Blood

Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish Blood

Traditionally used in Chinese medicine to eliminate/reduce/remove/resolve/dissipate blood-stasis

Traditionally used in Chinese medicine to clear/dry/drain/eliminate/resolve dampness

Traditionally used in Chinese medicine to dispel/expel/disperse/clear internal/endogenous heat

Traditionally used in Chinese medicine to remove Heat toxin

Traditionally used in Chinese medicine to dispel/expel/disperse/clear external/exogenous wind

#### 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.

Product presentation must only refer to detoxification in relation to natural body processes.

Product presentation must not imply or refer to serious cardiovascular conditions.

Product presentation must not imply or refer to drugs/alcohol.

#### Standard Indications

No Standard Indications included on Record

#### **Specific Indications**

No Specific Indications included on Record

#### Warnings

For practitioner dispensing only.

## **Additional Product information**

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Pack Size/Poison information			
Pack Size		Poison Schedule	
Components			
1 . Formulation 1			
Dosage Form	Capsule, hard		
Route of Administration	Oral		
Visual Identification	Grai		
Active Ingredients			
-	Extract day concentrate		40.6
Angelica polymorpha root Extract dry concentrate  Equivalent: Angelica polymorpha (Dry)			<b>18.6 mg</b> 111.6 mg
Artemisia frigida herb Extract dry concentrate			18.6 mg
Equivalent: Artemisia frigida (Dry)			111.6 mg
Astragalus membranaceus root Extract dry concentrate			18.6 mg
Equivalent: Astragalus membranaceus (Dry)			111.6 mg
Bassia scoparia fruit Extract dry concentrate			27.9 mg
Equivalent: Bassia scoparia (Dry)			167.4 mg
Citrus reticulata fruit peel Extract dry concentrate			11.1 mg
Equivalent: Citrus reticulata (Dry)			66.6 mg
Cynanchum stauntonii root Extract dry concentrate			16.5 mg
Equivalent: Cynanchum stauntonii (Dry)			99 mg
Dictamnus desycarpus stem bark Extract dry concentrate			18.6 mg
Equivalent: Dictamnus desycarpus (Dry)			111.6 mg
Glycyrrhiza uralensis root Extract dry concentrate			9 mg
Equivalent: Glycyrrhiza uralensis (Dry)			54 mg
Ligusticum striatum root Extract dry concentrate			16.5 mg
Equivalent: Ligusticum striatum (Dry)			99 mg
Lonicera japonica flower Extract dry concentrate			18.6 mg
Equivalent: Lonicera japonica (Dry)			111.6 mg
Paeonia veitchii root Extract dry concentrate			18.6 mg
Equivalent: Paeonia veitchii (Dry)			111.6 mg
Rehmannia glutinosa root Extract dry concentrate			18.6 mg
Equivalent: Rehmannia glutinosa (Dry)			111.6 mg
Salvia miltiorrhiza root Extract dry concentrate			18.6 mg
Equivalent: Salvia miltiorrhiza (Dry)			111.6 mg
Saposhnikovia divaricata root Extract dry concentrate			18.6 mg
Equivalent: Saposhnikovia divaricata (Dry)			111.6 mg
Scutellaria baicalensis root Extract dry concentrate			18.6 mg
Equivalent: Scutellaria baicalensis (Dry)			111.6 mg
Sophora flavescens root Extract dry concentrate			16.5 mg
Equivalent: Sophora flavescens (Dry)			99 mg
Tribulus terrestris fruit Extract dry concentrate  Equivalent: Tribulus terrestris (Dry)			16.5 mg
Equivalent: Tribulus terres	(DIX)		99 mg

# Other Ingredients (Excipients)

hydrolysed gelatin soluble maize starch titanium dioxide

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