



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	340450	Long Dan Xie Gan Tang a.k.a. Gentiana & Gardenia Anti-inflamm. Formula
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Sun Herbal Pty Ltd	
<b>Postal Address</b>	Unit 5/25 Garema Cct, Kingsgrove, NSW, 2208 Australia	
<b>ARTG Start Date</b>	29/07/2020	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 . Long Dan Xie Gan Tang a.k.a. Gentiana & Gardenia Anti-inflamm. Formula

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	29/07/2020
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#### Permitted Indications

Traditionally used in Chinese medicine to clear/expel damp-heat from the gallbladder

Traditionally used in Chinese medicine to clear/expel damp-heat from the liver

#### 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.

Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

#### 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

<b>Pack Size</b>	<b>Poison Schedule</b>
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#### Components

##### 1 . Formulation 1

<b>Dosage Form</b>	Capsule, hard
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**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Alisma plantago aquatica rhizome Extract dry concentrate</b>	<b>32.13 mg</b>
Equivalent: Alisma plantago aquatica (Dry)	192.78 mg
<b>Angelica polymorpha root Extract dry concentrate</b>	<b>21.42 mg</b>
Equivalent: Angelica polymorpha (Dry)	128.52 mg
<b>Bupleurum falcatum root Extract dry concentrate</b>	<b>32.13 mg</b>
Equivalent: Bupleurum falcatum (Dry)	192.78 mg
<b>Gardenia jasminoides fruit Extract dry concentrate</b>	<b>32.13 mg</b>
Equivalent: Gardenia jasminoides (Dry)	192.78 mg
<b>Gentiana scabra root Extract dry concentrate</b>	<b>32.13 mg</b>
Equivalent: Gentiana scabra (Dry)	192.78 mg
<b>Glycyrrhiza uralensis root Extract dry concentrate</b>	<b>10.77 mg</b>
Equivalent: Glycyrrhiza uralensis (Dry)	64.62 mg
<b>Plantago asiatica seed Extract dry concentrate</b>	<b>42.87 mg</b>
Equivalent: Plantago asiatica (Dry)	257.22 mg
<b>Rehmannia glutinosa root Extract dry concentrate</b>	<b>42.87 mg</b>
Equivalent: Rehmannia glutinosa (Dry)	257.22 mg
<b>Scutellaria baicalensis root Extract dry concentrate</b>	<b>32.13 mg</b>
Equivalent: Scutellaria baicalensis (Dry)	192.78 mg
<b>Tetrapanax papyrifer stem pith Extract dry concentrate</b>	<b>21.42 mg</b>
Equivalent: Tetrapanax papyrifer (Dry)	128.52 mg

**Other Ingredients (Excipients)**

**Agar**

**carrageenan**

**hypromellose**

**sodium citrate**

**soluble maize starch**

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