



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	388656	Long Dan Xie Gan Tang a.k.a. Anti-inflamm. 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	18/05/2022	
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 . Long Dan Xie Gan Tang a.k.a. Anti-inflamm. Formula

Product Type	Single Medicine Product	Effective Date	18/05/2022
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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 dispel/expel/disperse/clear fire in/of Liver-gallbladder excess Heat pattern

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

Traditionally used in Chinese medicine to anti-inflammatory/relieve inflammation in/of Damp-Heat in the Gallbladder pattern

Traditionally used in Chinese medicine to anti-inflammatory/relieve inflammation in/of Liver Fire pattern

Indication Requirements

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

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.

Label statement: If symptoms persist, talk to your health professional.

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

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Capsule, hard
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Route of Administration Oral

Visual Identification

Active Ingredients

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

Other Ingredients (Excipients)

hydrolysed gelatin
soluble maize starch
titanium dioxide

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