

**Australian Government** 

## **Department of Health**

# Therapeutic Goods Administration

## **Public Summary**

Summary for ARTG Entry:	171403	CLEAR THE LIVER FORMULA a.k.a. Qing Gan Qu Zhi Fang
ARTG entry for	Medicine Listed	
Sponsor	Sun Herbal Pty I	_td
Postal Address	Unit 5/25 Garem Australia	a Cct, Kingsgrove, NSW, 2208
ARTG Start Date	14/05/2010	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	5

## 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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 . CLEAR THE LIVER FORMULA a.k.a. Qing Gan Qu Zhi Fang

### Product Type

Single Medicine Product

Effective Date 2/05/2018

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 dispel/expel/disperse/clear internal/endogenous heat

Traditionally used in Chinese medicine to regulate Qi

Traditionally used in Chinese medicine to calm/soothe/nourish 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 serious cardiovascular conditions.

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.

This product may have a laxative effect.

Page 1 of 2

## This is not an ARTG Certificate document.

Produced at 31.08.2021 at 05:09:58 AEST

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**Department of Health** Therapeutic Goods Administration

Additional Product information

Pack Size/Poison information			
Pack Size		Poison Schedule	
Components			
1. Formulation 1			
Dosage Form C	apsule, hard		
Route of Administration O	ral		
Visual Identification			
Active Ingredients			
Bupleurum falcatum root Extr	act dry concentrate	30 mg	
Equivalent: Bupleurum falcatu	ım (Dry)	180 mg	
Chrysanthemum sinense flow	er Extract dry concentrate	30 mg	
Equivalent: Chrysanthemum s	sinense (Dry)	180 mg	
Citrus aurantium fruit Extract dry concentrate		30 mg	
Equivalent: Citrus aurantium (Dry)		180 mg	
Crataegus pinnatifida fruit Ext	tract dry concentrate	39.9 mg	
Equivalent: Crataegus pinnatifida (Dry)		239.4 mg	
Curcuma longa tuber Extract	dry concentrate	39.9 mg	
Equivalent: Curcuma longa (Dry)		239.4 mg	
Glycyrrhiza uralensis root Ext	tract dry concentrate	20.4 mg	
Equivalent: Glycyrrhiza uralensis (Dry)		122.4 mg	
Paeonia veitchii root Extract o	iry concentrate	30 mg	
Equivalent: Paeonia veitchii (I	Dry)	180 mg	
Salvia miltiorrhiza root Extrac	t dry concentrate	39.9 mg	
Equivalent: Salvia miltiorrhiza	(Dry)	239.4 mg	
Senna tora seed Extract dry c	oncentrate	39.9 mg	
Equivalent: Senna tora (Dry)		239.4 mg	
Other Ingredients (Excipients	)		
Agar			
carrageenan			
hypromellose			
sodium citrate dihydrate			
soluble maize starch			

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