

# **Australian Government**

### **Department of Health**

## Therapeutic Goods Administration

#### **Public Summary**

Summary for ARTG Entry: 189257 QI MOVER FORMULA a.k.a. Chai Hu Shu Gan San

ARTG entry for Medicine Listed

Sponsor Sun Herbal Pty Ltd

Postal Address Unit 5/25 Garema Cct, Kingsgrove, NSW, 2208

Australia

ARTG Start Date 13/09/2011

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.

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 . QI MOVER FORMULA a.k.a. Chai Hu Shu Gan San

Product Type Single Medicine Product Effective Date 19/04/2018

#### **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 regulate/soothe/smooth/disperse the flow of liver-qi/liver

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.

#### **Additional Product information**

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## **Australian Government**

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## Therapeutic Goods Administration

Pack	Size	/Poison	inf	ormation
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Pack Size Poison Schedule

#### Components

#### 1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

#### **Active Ingredients**

Nouve ingrediente			
Bupleurum falcatum root Extract dry concentrate			
Equivalent: Bupleurum falcatum (Dry)	207.72 mg		
Citrus aurantium fruit Extract dry concentrate			
Equivalent: Citrus aurantium (Dry)	276.84 mg		
Corydalis turtschaninovii rhizome Extract dry concentrate			
Equivalent: Corydalis turtschaninovii (Dry)	207.72 mg		
Curcuma longa tuber Extract dry concentrate			
Equivalent: Curcuma longa (Dry)	207.72 mg		
Cyperus rotundus rhizome Extract dry concentrate			
Equivalent: Cyperus rotundus (Dry)	276.84 mg		
Glycyrrhiza uralensis root Extract dry concentrate			
Equivalent: Glycyrrhiza uralensis (Dry)	138.42 mg		
Ligusticum striatum rhizome Extract dry concentrate			
Equivalent: Ligusticum striatum (Dry)	207.72 mg		
Paeonia lactiflora root Extract dry concentrate			
Equivalent: Paeonia lactiflora (Dry)	277.02 mg		

#### Other Ingredients (Excipients)

#### Agar

carrageenan

hypromellose

sodium citrate dihydrate

soluble maize starch

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