



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 171397 SETTLE THE EMOTIONS FORMULA a.k.a. Yi 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 14/05/2010
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 . SETTLE THE EMOTIONS FORMULA a.k.a. Yi Gan San

Product Type	Effective Date
Single Medicine Product	4/05/2018

Permitted Indications

Traditionally used in Chinese medicine to nourish/tonify/replenish strengthen liver-blood
Traditionally used in Chinese medicine to regulate/soothe/smooth/disperse the flow of liver-qi/liver
Traditionally used in Chinese medicine to dispel/expel/extinguish/disperse/clear exogenous wind
Traditionally used in Chinese medicine to calm/soothe/nourish the liver
Traditionally used in Chinese medicine to clear/expel/dissolve/resolve Phlegm

Indication Requirements

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
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 serious cardiovascular conditions.
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.

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Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Angelica polymorpha root Extract dry concentrate	36 mg
Equivalent: Angelica polymorpha (Dry)	216 mg
Atractylodes macrocephala rhizome Extract dry concentrate	36 mg
Equivalent: Atractylodes macrocephala (Dry)	216 mg
Bupleurum falcatum root Extract dry concentrate	18 mg
Equivalent: Bupleurum falcatum (Dry)	108 mg
Citrus reticulata fruit pericarp Extract dry concentrate	36 mg
Equivalent: Citrus reticulata (Dry)	216 mg
Glycyrrhiza uralensis root Extract dry concentrate	18 mg
Equivalent: Glycyrrhiza uralensis (Dry)	108 mg
Ligusticum striatum rhizome Extract liquid concentrate	30 mg
Equivalent: Ligusticum striatum (Dry)	180 mg
Pinellia ternata tuber Extract dry concentrate	54 mg
Equivalent: Pinellia ternata (Dry)	324 mg
Uncaria rhynchophylla stem Extract dry concentrate	36 mg
Equivalent: Uncaria rhynchophylla (Dry)	216 mg
Wolfiporia cocos hyphae Extract dry concentrate	36 mg
Equivalent: Wolfiporia cocos (Dry)	216 mg

Other Ingredients (Excipients)

Agar

carrageenan

hypromellose

sodium citrate dihydrate

soluble maize starch

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