

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 266762 Yin Qiao Sang Ju Gan Mao Ling a.k.a. CNF Relief 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 4/01/2016
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 . Yin Qiao Sang Ju Gan Mao Ling a.k.a. CNF Relief Formula

Product Type Single Medicine Product Effective Date 13/12/2019

Permitted Indications

Traditionally used in Chinese medicine to release Exterior

Traditionally used in Chinese medicine to remove Heat toxin

Traditionally used in Chinese medicine to disseminate/diffuse lungs/lung-qi

Traditionally used in Chinese medicine to dispel/expel/extinguish/disperse/clear wind-heat

Traditionally used in Chinese medicine to decrease/reduce/relieve cough

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.

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

Product presentation must only refer to detoxification in relation to natural body processes.

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

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 drugs/alcohol.

Product presentation must not imply or refer to disease in any body organ.

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

Standard Indications

No Standard Indications included on Record

Specific Indications

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No Specific Indications included on Record

Warnings

For practitioner dispensing only.

If symptoms persist consult your healthcare practitioner (or words to that effect).

If coughing persists consult your doctor (or a healthcare professional) (or words to that effect).

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).

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

Active Ingredients	
Chrysanthemum sinense flower Extract dry concentrate	11.19 mg
Equivalent: Chrysanthemum sinense (Dry)	67.14 mg
forsythia suspensa fruit Extract dry concentrate	22.35 mg
Equivalent: forsythia suspensa (Dry)	134.1 mg
Glycine max seed Extract dry concentrate	16.77 mg
Equivalent: Glycine max (Dry)	100.62 mg
Glycyrrhiza uralensis root Extract dry concentrate	9.3 mg
Equivalent: Glycyrrhiza uralensis (Dry)	55.8 mg
Isatis tinctoria root Extract dry concentrate	33.54 mg
Equivalent: Isatis tinctoria (Dry)	201.24 mg
Isatis tinctoria leaf Extract dry concentrate	33.54 mg
Equivalent: Isatis tinctoria (Dry)	201.24 mg
Lonicera japonica flower Extract dry concentrate	33.54 mg
Equivalent: Lonicera japonica (Dry)	201.24 mg
Mentha haplocalyx herb Extract dry concentrate	16.77 mg
Equivalent: Mentha haplocalyx (Dry)	100.62 mg
Morus alba leaf Extract dry concentrate	16.77 mg
Equivalent: Morus alba (Dry)	100.62 mg
Phragmites australis rhizome Extract dry concentrate	22.35 mg
Equivalent: Phragmites australis (Dry)	134.1 mg
Platycodon grandiflorus root Extract dry concentrate	11.19 mg
Equivalent: Platycodon grandiflorus (Dry)	67.14 mg
Prunus armeniaca seed endosperm Extract dry concentrate	16.77 mg
Equivalent: Prunus armeniaca (Dry)	100.62 mg
Saposhnikovia divaricata root Extract dry concentrate	16.77 mg
Equivalent: Saposhnikovia divaricata (Dry)	100.62 mg
Schizonepeta tenuifolia herb top flowering Extract dry concentrate	11.19 mg
Equivalent: Schizonepeta tenuifolia (Dry)	67.14 mg
Scutellaria baicalensis root Extract dry concentrate	27.96 mg
Equivalent: Scutellaria baicalensis (Dry)	167.76 mg
Other Ingredients (Excipients)	

Agar



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carrageenan hypromellose sodium citrate dihydrate soluble maize starch

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