



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

| | | |
|--------------------------------|----------------------------------------------------------|--------------------------------------------------|
| Summary for ARTG Entry: | 99221 | Yin Qiao Wan a.k.a. Lonicera & Forsythia 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 | 19/01/2004 | |
| 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 Wan a.k.a. Lonicera & Forsythia Formula

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 12/04/2018 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

Traditionally used in Chinese medicine to remove Heat toxin

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

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 drugs/alcohol.

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.

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

Public Summary



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Pill
Route of Administration Oral

Visual Identification

Active Ingredients

| | |
|---------------------------------------------------------------------------|------------------|
| Arctium lappa seed Extract dry concentrate | 21.933 mg |
| Equivalent: Arctium lappa (Dry) | 47.475 mg |
| Forsythia suspensa fruit Extract dry concentrate | 26.317 mg |
| Equivalent: Forsythia suspensa (Dry) | 56.962 mg |
| Glycine max seed Extract dry concentrate | 21.933 mg |
| Equivalent: Glycine max (Dry) | 47.475 mg |
| Glycyrrhiza uralensis root Extract dry concentrate | 10.949 mg |
| Equivalent: Glycyrrhiza uralensis (Dry) | 23.7 mg |
| Lonicera japonica flower Extract dry concentrate | 26.317 mg |
| Equivalent: Lonicera japonica (Dry) | 56.962 mg |
| Mentha haplocalyx herb Extract dry concentrate | 10.967 mg |
| Equivalent: Mentha haplocalyx (Dry) | 23.737 mg |
| Phragmites australis rhizome Extract dry concentrate | 21.933 mg |
| Equivalent: Phragmites australis (Dry) | 47.475 mg |
| Phyllostachys nigra leaf Extract dry concentrate | 10.967 mg |
| Equivalent: Phyllostachys nigra (Dry) | 23.737 mg |
| Platycodon grandiflorus root Extract dry concentrate | 10.967 mg |
| Equivalent: Platycodon grandiflorus (Dry) | 23.737 mg |
| Schizonepeta tenuifolia herb top flowering Extract dry concentrate | 10.967 mg |
| Equivalent: Schizonepeta tenuifolia (Dry) | 23.737 mg |

Other Ingredients (Excipients)

soluble maize starch

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary