



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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| Summary for ARTG Entry: | 333642 | Tong Xie Yao Fang (Jia Wei) a.k.a. Peony & Citrus Irritable Bowel 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 | 7/04/2020 | |
| 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.

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 . Tong Xie Yao Fang (Jia Wei) a.k.a. Peony & Citrus Irritable Bowel Formula

| | | | |
|---------------------|-------------------------|-----------------------|-----------|
| Product Type | Single Medicine Product | Effective Date | 7/04/2020 |
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Permitted Indications

- Traditionally used in Chinese medicine to clear/dry/drain/eliminate/resolve dampness
- Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish/fortify/invigorate spleen
- 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 liver disease, such as cirrhosis, hepatitis.
- Product presentation must not imply or refer to disease in any body organ.

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

| | |
|------------------|------------------------|
| Pack Size | Poison Schedule |
|------------------|------------------------|

Components

- 1 . Formulation 1

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Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

| | |
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| Amomum aromaticum fruit Extract dry concentrate | 16.2 mg |
| Equivalent: Amomum aromaticum (Dry) | 97.2 mg |
| Atractylodes lancea rhizome Extract dry concentrate | 24 mg |
| Equivalent: Atractylodes lancea (Dry) | 144 mg |
| Atractylodes macrocephala rhizome Extract dry concentrate | 24 mg |
| Equivalent: Atractylodes macrocephala (Dry) | 144 mg |
| Citrus reticulata fruit peel Extract dry concentrate | 16.2 mg |
| Equivalent: Citrus reticulata (Dry) | 97.2 mg |
| Codonopsis pilosula root Extract dry concentrate | 31.8 mg |
| Equivalent: Codonopsis pilosula (Dry) | 190.8 mg |
| Coix lachryma-jobi seed Extract dry concentrate | 24 mg |
| Equivalent: Coix lachryma-jobi (Dry) | 144 mg |
| Cyperus rotundus rhizome Extract dry concentrate | 24 mg |
| Equivalent: Cyperus rotundus (Dry) | 144 mg |
| Dioscorea oppositifolia root Extract dry concentrate | 24 mg |
| Equivalent: Dioscorea oppositifolia (Dry) | 144 mg |
| Dolichos lablab seed Extract dry concentrate | 24 mg |
| Equivalent: Dolichos lablab (Dry) | 144 mg |
| Glycyrrhiza uralensis root Extract dry concentrate | 12 mg |
| Equivalent: Glycyrrhiza uralensis (Dry) | 72 mg |
| Hordeum vulgare sprout Extract dry concentrate | 24 mg |
| Equivalent: Hordeum vulgare (Dry) | 144 mg |
| Paeonia lactiflora root Extract dry concentrate | 31.8 mg |
| Equivalent: Paeonia lactiflora (Dry) | 190.8 mg |
| Ziziphus jujuba fruit Extract dry concentrate | 24 mg |
| Equivalent: Ziziphus jujuba (Dry) | 144 mg |

Other Ingredients (Excipients)

Agar

carrageenan

hypromellose

sodium citrate dihydrate

soluble maize starch

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