



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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| Summary for ARTG Entry: | 106550 | Bi Min Gan Te Xiao Fang a.k.a. Magnolia & Scutellaria Hafever 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 | 28/07/2004 | |
| 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 . Bi Min Gan Te Xiao Fang a.k.a. Magnolia & Scutellaria Hafever Formula

| | | | |
|---------------------|-------------------------|-----------------------|-----------|
| Product Type | Single Medicine Product | Effective Date | 6/04/2018 |
|---------------------|-------------------------|-----------------------|-----------|

Permitted Indications

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

Traditionally used in Chinese medicine to unblock/clear nasal passages

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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

For practitioner dispensing only.

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

Additional Product information

Pack Size/Poison information

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



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Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

| | |
|---|------------------|
| Anemone altaica rhizome Extract dry concentrate | 22.387 mg |
| Equivalent: Anemone altaica (Dry) | 135 mg |
| Angelica dahurica root Extract dry concentrate | 22.387 mg |
| Equivalent: Angelica dahurica (Dry) | 135 mg |
| Chrysanthemum sinense flower Extract dry concentrate | 29.85 mg |
| Equivalent: Chrysanthemum sinense (Dry) | 180 mg |
| Cinnamomum cassia twig Extract dry concentrate | 22.387 mg |
| Equivalent: Cinnamomum cassia (Dry) | 135 mg |
| Ledebouriella seseloides root Extract dry concentrate | 22.387 mg |
| Equivalent: Ledebouriella seseloides (Dry) | 135 mg |
| Magnolia liliflora flower bud Extract dry concentrate | 37.312 mg |
| Equivalent: Magnolia liliflora (Dry) | 225 mg |
| Mentha haplocalyx herb Extract dry concentrate | 37.312 mg |
| Equivalent: Mentha haplocalyx (Dry) | 225 mg |
| Morus alba leaf Extract dry concentrate | 37.312 mg |
| Equivalent: Morus alba (Dry) | 225 mg |
| Schizonepeta tenuifolia herb top flowering Extract dry concentrate | 22.387 mg |
| Equivalent: Schizonepeta tenuifolia (Dry) | 135 mg |
| Scutellaria baicalensis root Extract dry concentrate | 22.387 mg |
| Equivalent: Scutellaria baicalensis (Dry) | 135 mg |
| Xanthium sibiricum fruit Extract dry concentrate | 22.387 mg |
| Equivalent: Xanthium sibiricum (Dry) | 135 mg |

Other Ingredients (Excipients)

hydrolysed gelatin

soluble maize starch

titanium dioxide

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