



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

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.

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	19/09/2024
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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

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

For practitioner dispensing only.

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

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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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