



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	329800	Pi Fu Bing Jie Du Fang a.k.a. Acute Eczema 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	12/02/2020	
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.

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 . Pi Fu Bing Jie Du Fang a.k.a. Acute Eczema Formula

Product Type	Single Medicine Product	Effective Date	12/02/2020
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Permitted Indications

Traditionally used in Chinese medicine to clear/dry/drain/eliminate/resolve dampness in/of Damp-Heat pattern

Traditionally used in Chinese medicine to remove Heat toxin

Traditionally used in Chinese medicine to dispel/expel/extinguish/disperse/clear exogenous wind in/of exterior excess pattern

Indication Requirements

Product presentation must not imply or refer to drugs/alcohol.

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

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 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.

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

Additional Product information



Australian Government
Department of Health
Therapeutic Goods Administration

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Angelica dahurica root Extract dry concentrate	22.2 mg
Equivalent: Angelica dahurica (Dry)	133.2 mg
Bassia scoparia fruit Extract dry concentrate	22.2 mg
Equivalent: Bassia scoparia (Dry)	133.2 mg
Cynanchum stauntonii root Extract dry concentrate	22.2 mg
Equivalent: Cynanchum stauntonii (Dry)	133.2 mg
Dictamnus desycarpus stem bark Extract dry concentrate	22.2 mg
Equivalent: Dictamnus desycarpus (Dry)	133.2 mg
Gardenia jasminoides fruit Extract dry concentrate	29.4 mg
Equivalent: Gardenia jasminoides (Dry)	176.4 mg
Glycyrrhiza uralensis root Extract dry concentrate	12 mg
Equivalent: Glycyrrhiza uralensis (Dry)	72 mg
Lonicera japonica flower Extract dry concentrate	36.9 mg
Equivalent: Lonicera japonica (Dry)	221.4 mg
Plantago asiatica herb Extract dry concentrate	29.4 mg
Equivalent: Plantago asiatica (Dry)	176.4 mg
Schizonepeta tenuifolia herb top flowering Extract dry concentrate	22.2 mg
Equivalent: Schizonepeta tenuifolia (Dry)	133.2 mg
Scutellaria baicalensis root Extract dry concentrate	22.2 mg
Equivalent: Scutellaria baicalensis (Dry)	133.2 mg
Smilax glabra rhizome Extract dry concentrate	36.9 mg
Equivalent: Smilax glabra (Dry)	221.4 mg
Sophora flavescens root Extract dry concentrate	22.2 mg
Equivalent: Sophora flavescens (Dry)	133.2 mg

Other Ingredients (Excipients)

Agar

carrageenan

hypromellose

sodium citrate

soluble maize starch

Public Summary

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