



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	110614	Zhi Bai Ba Wei Wan a.k.a. A. P. & Rehmannia Empty Heat 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	30/09/2004	
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 . Zhi Bai Ba Wei Wan a.k.a. A. P. & Rehmannia Empty Heat Formula

Product Type	Single Medicine Product	Effective Date	8/05/2018
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Permitted Indications

Traditionally used in Chinese medicine to clear/cool/drain/purge/asthenic-heat/deficiency-heat

Traditionally used in Chinese medicine to dispel/expel/disperse/clear fire in/of Kidney Yin Deficiency pattern

Traditionally used in Chinese medicine to nourish/tonify/replenish kidney-yin

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 kidney disease.

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
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Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Alisma plantago aquatica rhizome Extract dry concentrate	37.31 mg
Equivalent: Alisma plantago aquatica (Dry)	225 mg
Anemarrhena asphodeloides rhizome Extract dry concentrate	24.87 mg
Equivalent: Anemarrhena asphodeloides (Dry)	149.94 mg
Cornus officinalis fruit Extract dry concentrate	24.87 mg
Equivalent: Cornus officinalis (Dry)	149.94 mg
Dioscorea oppositifolia root Extract dry concentrate	49.76 mg
Equivalent: Dioscorea oppositifolia (Dry)	300.06 mg
Paeonia suffruticosa stem bark Extract dry concentrate	24.87 mg
Equivalent: Paeonia suffruticosa (Dry)	149.94 mg
Phellodendron amurense stem bark Extract dry concentrate	24.87 mg
Equivalent: Phellodendron amurense (Dry)	149.94 mg
Rehmannia glutinosa root Extract dry concentrate	74.63 mg
Equivalent: Rehmannia glutinosa (Dry)	450 mg
Wolfiporia cocos fruiting body Extract dry concentrate	37.34 mg
Equivalent: Wolfiporia cocos (Dry)	225.18 mg

Other Ingredients (Excipients)

hydrolysed gelatin

soluble maize starch

titanium dioxide

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