



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	342372	Jin Gui Suan Zao Ren Tang a.k.a Ziziphus Combination
ARTG entry for	Medicine Listed	
Sponsor	Sun Herbal Pty Ltd	
Postal Address	Unit 5/25 Garema Cct, Kingsgrove, NSW, 2208 Australia	
ARTG Start Date	26/08/2020	
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 . Jin Gui Suan Zao Ren Tang a.k.a Ziziphus Combination

Product Type	Single Medicine Product	Effective Date	26/08/2020
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Permitted Indications

- Traditionally used in Chinese medicine to nourish/tonify/replenish strengthen liver-blood
- Traditionally used in Chinese medicine to clear/cool/drain/purge/asthenic-heat/deficiency-heat
- Traditionally used in Chinese medicine to calm/soothe/nourish/balance spirit

Indication Requirements

- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- 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 serious cardiovascular conditions.

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

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Dosage Form Pill

Route of Administration Oral

Visual Identification

Active Ingredients

Albizia julibrissin flower Extract dry concentrate	17.33 mg
Equivalent: Albizia julibrissin (Dry)	37.43 mg
Anemarrhena asphodeloides rhizome Extract dry concentrate	23.1 mg
Equivalent: Anemarrhena asphodeloides (Dry)	49.896 mg
Angelica polymorpha root Extract dry concentrate	23.1 mg
Equivalent: Angelica polymorpha (Dry)	49.896 mg
Glycyrrhiza uralensis root Extract dry concentrate	9.63 mg
Equivalent: Glycyrrhiza uralensis (Dry)	20.81 mg
Ligusticum striatum rhizome Extract dry concentrate	17.33 mg
Equivalent: Ligusticum striatum (Dry)	37.43 mg
Paeonia lactiflora root Extract dry concentrate	23.1 mg
Equivalent: Paeonia lactiflora (Dry)	49.896 mg
Polygala sibirica root Extract dry concentrate	9.63 mg
Equivalent: Polygala sibirica (Dry)	20.81 mg
Wolfiporia cocos hyphae Extract dry concentrate	23.1 mg
Equivalent: Wolfiporia cocos (Dry)	49.896 mg
Ziziphus jujuba var. spinosa seed Extract dry concentrate	28.7 mg
Equivalent: Ziziphus jujuba var. spinosa (Dry)	61.99 mg

Other Ingredients (Excipients)

soluble maize starch

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