



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	342366	Er Xian Gan Mai Da Zao Fang a.k.a. Menopause #2 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	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 . Er Xian Gan Mai Da Zao Fang a.k.a. Menopause #2 Formula

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

- Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish/invigorate heart-blood
- Traditionally used in Chinese medicine to dispel/expel/disperse/clear fire in/of Kidney Qi Deficiency pattern
- Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish heart Qi
- Traditionally used in Chinese medicine to enrich/nourish/tonify/fortify/strengthen kidneys
- Traditionally used in Chinese medicine to calm/soothe/nourish/balance spirit

Indication Requirements

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

'Contains gluten (or words to that effect)'

Additional Product information

Pack Size/Poison information



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Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Albizia julibrissin stem bark Extract dry concentrate	19.8 mg
Equivalent: Albizia julibrissin (Dry)	118.8 mg
Chrysanthemum sinense flower Extract dry concentrate	13.2 mg
Equivalent: Chrysanthemum sinense (Dry)	79.2 mg
Curculigo orchioides rhizome Extract dry concentrate	19.8 mg
Equivalent: Curculigo orchioides (Dry)	118.8 mg
Epimedium sagittatum herb Extract dry concentrate	19.8 mg
Equivalent: Epimedium sagittatum (Dry)	118.8 mg
Eucommia ulmoides stem bark Extract dry concentrate	19.8 mg
Equivalent: Eucommia ulmoides (Dry)	118.8 mg
Glycyrrhiza uralensis root Extract dry concentrate	11.1 mg
Equivalent: Glycyrrhiza uralensis (Dry)	66.6 mg
Lilium brownii bulb Extract dry concentrate	22.2 mg
Equivalent: Lilium brownii (Dry)	133.2 mg
Loranthus parasiticus stem Extract dry concentrate	19.8 mg
Equivalent: Loranthus parasiticus (Dry)	118.8 mg
Lycium barbarum fruit Extract dry concentrate	19.8 mg
Equivalent: Lycium barbarum (Dry)	118.8 mg
Morinda officinalis root Extract dry concentrate	13.2 mg
Equivalent: Morinda officinalis (Dry)	79.2 mg
Rehmannia glutinosa root Extract dry concentrate	33 mg
Equivalent: Rehmannia glutinosa (Dry)	198 mg
Triticum aestivum seed Extract dry concentrate	66.3 mg
Equivalent: Triticum aestivum (Dry)	397.8 mg
Ziziphus jujuba fruit Extract dry concentrate	22.2 mg
Equivalent: Ziziphus jujuba (Dry)	133.2 mg

Other Ingredients (Excipients)

hydrolysed gelatin

titanium dioxide

Public Summary

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