



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	229317	TCM MENO EZE - Er Xian Tang Tablet
ARTG entry for	Medicine Listed	
Sponsor	Cathay Herbal Laboratories	
Postal Address	P O Box 6318, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	14/10/2014	
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 . TCM MENO EZE - Er Xian Tang Tablet

Product Type	Single Medicine Product	Effective Date	15/04/2019
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Permitted Indications

Traditionally used in Chinese medicine to clear/cool/drain/purge/asthenic-heat/deficiency-heat in/of Heat Deficiency pattern before eating in adults

Traditionally used in Chinese medicine to warm and nourish/strengthen/tonify/enrich kidneys/kidney-yang in/of Kidney Yang Deficiency pattern before eating in adults

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

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

Keep out of reach of children (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 Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Anemarrhena asphodeloides rhizome Extract dry concentrate	67.5 mg
Equivalent: Anemarrhena asphodeloides (Dry)	1.553 g
Angelica polymorpha root Extract dry concentrate	67.5 mg
Equivalent: Angelica polymorpha (Dry)	1.553 g
Curculigo orchoides rhizome Extract dry concentrate	90 mg
Equivalent: Curculigo orchoides (Dry)	1.35 g
Epimedium sagittatum herb Extract dry concentrate	90 mg
Equivalent: Epimedium sagittatum (Dry)	1.35 g
Morinda officinalis root Extract dry concentrate	67.5 mg
Equivalent: Morinda officinalis (Dry)	1.013 g
Phellodendron chinense stem bark Extract dry concentrate	67.5 mg
Equivalent: Phellodendron chinense (Dry)	1.013 g

Other Ingredients (Excipients)

hypromellose

magnesium stearate

microcrystalline cellulose

purified talc

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