



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	148047	Qiang Xin Shen Mai Jiao Nang a.k.a. Cardiac 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	4/12/2007	
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 . Qiang Xin Shen Mai Jiao Nang a.k.a. Cardiac Formula

Product Type	Single Medicine Product	Effective Date	5/04/2018
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Permitted Indications

Traditionally used in Chinese medicine to invigorate/activate Blood
Traditionally used in Chinese medicine to replenish/nourish body-fluid
Traditionally used in Chinese medicine to regulate Qi
Traditionally used in Chinese medicine to soothe/descend Qi
Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish Qi
Traditionally used in Chinese medicine to nourish yin/yin element/stratum
Traditionally used in Chinese medicine to clear/expel/dissolve/resolve Phlegm

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.

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.

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings



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Therapeutic Goods Administration

For practitioner dispensing only.

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

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Allium macrostemon bulb Extract dry concentrate	18.63 mg
Equivalent: Allium macrostemon (Dry)	111.78 mg
Cinnamomum cassia twig Extract dry concentrate	13.95 mg
Equivalent: Cinnamomum cassia (Dry)	83.7 mg
Citrus aurantium fruit Extract dry concentrate	27.99 mg
Equivalent: Citrus aurantium (Dry)	167.94 mg
Curcuma longa tuber Extract dry concentrate	27.99 mg
Equivalent: Curcuma longa (Dry)	167.94 mg
Ophiopogon japonicus tuber Extract dry concentrate	37.32 mg
Equivalent: Ophiopogon japonicus (Dry)	223.92 mg
Panax ginseng root Extract dry concentrate	37.32 mg
Equivalent: Panax ginseng (Dry)	223.92 mg
Pinellia ternata tuber Extract dry concentrate	27.99 mg
Equivalent: Pinellia ternata (Dry)	167.94 mg
Salvia miltiorrhiza root Extract dry concentrate	37.32 mg
Equivalent: Salvia miltiorrhiza (Dry)	223.92 mg
Santalum album stem heartwood Extract dry concentrate	15.51 mg
Equivalent: Santalum album (Dry)	93.06 mg
Schisandra chinensis fruit Extract dry concentrate	27.99 mg
Equivalent: Schisandra chinensis (Dry)	167.94 mg
Trichosanthes kirilowii fruit Extract dry concentrate	27.99 mg
Equivalent: Trichosanthes kirilowii (Dry)	167.94 mg

Other Ingredients (Excipients)

hydrolysed gelatin

soluble maize starch

titanium dioxide

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