



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	197497	Tian Wang Bu Xin Dan a.k.a. Calm the Spirit Formula
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Sun Herbal Pty Ltd	
<b>Postal Address</b>	Unit 5/25 Garema Cct, Kingsgrove, NSW, 2208 Australia	
<b>ARTG Start Date</b>	15/05/2012	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 . Tian Wang Bu Xin Dan a.k.a. Calm the Spirit Formula

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	23/04/2018
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#### Permitted Indications

Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish Blood in/of Heart Yin Deficiency pattern

Traditionally used in Chinese medicine to nourish yin/yin element/stratum in/of Heart Yin Deficiency pattern

Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish heart-yin in/of Heart Yin Deficiency pattern

Traditionally used in Chinese medicine to calm/soothe/nourish/balance spirit in/of Heart Yin Deficiency pattern

#### Indication Requirements

Product presentation must not imply or refer to serious cardiovascular conditions.

Product presentation must not imply or refer to heart disease.

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

For practitioner dispensing only.

#### Additional Product information



Australian Government  
Department of Health and Aged Care  
Therapeutic Goods Administration

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

<b>Angelica polymorpha root Extract dry concentrate</b>	<b>24.9 mg</b>
Equivalent: Angelica polymorpha (Dry)	149.4 mg
<b>Asparagus cochinchinensis tuber Extract dry concentrate</b>	<b>24.9 mg</b>
Equivalent: Asparagus cochinchinensis (Dry)	149.4 mg
<b>Biota orientalis seed Extract dry concentrate</b>	<b>24.9 mg</b>
Equivalent: Biota orientalis (Dry)	149.4 mg
<b>Ophiopogon japonicus tuber Extract dry concentrate</b>	<b>24.9 mg</b>
Equivalent: Ophiopogon japonicus (Dry)	149.4 mg
<b>Platycodon grandiflorus root Extract dry concentrate</b>	<b>10.35 mg</b>
Equivalent: Platycodon grandiflorus (Dry)	62.1 mg
<b>Polygala sibirica root Extract dry concentrate</b>	<b>10.35 mg</b>
Equivalent: Polygala sibirica (Dry)	62.1 mg
<b>Pseudostellaria heterophylla root Extract dry concentrate</b>	<b>30.9 mg</b>
Equivalent: Pseudostellaria heterophylla (Dry)	185.4 mg
<b>Rehmannia glutinosa root Extract dry concentrate</b>	<b>30.9 mg</b>
Equivalent: Rehmannia glutinosa (Dry)	185.4 mg
<b>Salvia miltiorrhiza root Extract dry concentrate</b>	<b>30.9 mg</b>
Equivalent: Salvia miltiorrhiza (Dry)	185.4 mg
<b>Schisandra chinensis fruit Extract dry concentrate</b>	<b>18.6 mg</b>
Equivalent: Schisandra chinensis (Dry)	111.6 mg
<b>Scrophularia ningpoensis root Extract dry concentrate</b>	<b>18.6 mg</b>
Equivalent: Scrophularia ningpoensis (Dry)	111.6 mg
<b>Wolfiporia cocos fruiting body Extract dry concentrate</b>	<b>24.9 mg</b>
Equivalent: Wolfiporia cocos (Dry)	149.4 mg
<b>Ziziphus jujuba var. spinosa seed Extract dry concentrate</b>	<b>24.9 mg</b>
Equivalent: Ziziphus jujuba var. spinosa (Dry)	149.4 mg

Other Ingredients (Excipients)

Agar

carrageenan

hypromellose

sodium citrate dihydrate

soluble maize starch

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