



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

## Public Summary

**Summary for ARTG Entry:** 406812 REHMANNIA EIGHT VITALITY FORMULA a.k.a Fu Gui B Wei Tang

**ARTG entry for** Medicine Listed  
**Sponsor** Sun Herbal Pty Ltd  
**Postal Address** Unit 5/25 Garema Cct, Kingsgrove, NSW, 2208  
Australia  
**ARTG Start Date** 24/03/2023  
**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.

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 . REHMANNIA EIGHT VITALITY FORMULA a.k.a Fu Gui B Wei Tang

**Product Type** Single Medicine Product **Effective Date** 19/05/2023

#### Permitted Indications

Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish/fortify/invigorate spleen in/of Kidney Yang Deficiency pattern

Traditionally used in Chinese medicine to warm and nourish/strengthen/tonify/enrich kidneys/kidney-yang

Traditionally used in Chinese medicine to warm and nourish/strengthen stomach in/of Kidney Yang Deficiency pattern

#### Indication Requirements

Product presentation must not imply or refer to kidney 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 disease in any body organ.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

For practitioner dispensing only.

#### Additional Product information

#### Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

#### Pack Size/Poison information

**Pack Size** **Poison Schedule**

#### Components

1 . Formulation 1



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**Dosage Form** Capsule, hard

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Alisma plantago aquatica rhizome Extract dry concentrate</b>	<b>36 mg</b>
Equivalent: Alisma plantago aquatica (Dry)	216 mg
<b>Cinnamomum cassia stem bark Extract dry concentrate</b>	<b>24 mg</b>
Equivalent: Cinnamomum cassia (Dry)	144 mg
<b>Cornus officinalis fruit Extract dry concentrate</b>	<b>36 mg</b>
Equivalent: Cornus officinalis (Dry)	216 mg
<b>Dioscorea oppositifolia root Extract dry concentrate</b>	<b>48 mg</b>
Equivalent: Dioscorea oppositifolia (Dry)	288 mg
<b>Paeonia suffruticosa stem bark Extract dry concentrate</b>	<b>36 mg</b>
Equivalent: Paeonia suffruticosa (Dry)	216 mg
<b>Rehmannia glutinosa root Extract dry concentrate</b>	<b>48 mg</b>
Equivalent: Rehmannia glutinosa (Dry)	288 mg
<b>Wolfiporia cocos hyphae Extract dry concentrate</b>	<b>48 mg</b>
Equivalent: Wolfiporia cocos (Dry)	288 mg
<b>Zingiber officinale rhizome Extract dry concentrate</b>	<b>24 mg</b>
Equivalent: Zingiber officinale (Dry)	144 mg

**Other Ingredients (Excipients)**

hydrolysed gelatin

soluble maize starch

titanium dioxide

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