



**Australian Government**  
**Department of Health**  
**Therapeutic Goods Administration**

## Public Summary

|                                |  |   |
|--------------------------------|--|---|
| <b>Summary for ARTG Entry:</b> | 199645   | Fu Zhen Ding Chuan Fang A.K.A. Lung Function II 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<br>Australia |   |
| <b>ARTG Start Date</b>         | 31/07/2012   |   |
| <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 . Fu Zhen Ding Chuan Fang A.K.A. Lung Function II Formula

|                     |                         |                       |            |
|---------------------|-------------------------|-----------------------|------------|
| <b>Product Type</b> | Single Medicine Product | <b>Effective Date</b> | 21/04/2018 |
|---------------------|-------------------------|-----------------------|------------|

### Permitted Indications

Traditionally used in Chinese medicine to moisten lungs

Traditionally used in Chinese medicine to nourish/tonify/warm/boost/invigorate/strengthen kidney-essence/kidney-jing

Traditionally used in Chinese medicine to disseminate/diffuse lungs/lung-qi

Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish/fortify lungs/lung-qi

Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish spleen-qi

Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish lung-yin

Traditionally used in Chinese medicine to clear/expel/dissolve/resolve Phlegm

### 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 serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

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

Product presentation must not imply or refer to kidney disease.

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

### Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record



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#### Warnings

For practitioner dispensing only.

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

#### Additional Product information

#### Pack Size/Poison information

|                  |                        |
|------------------|------------------------|
| <b>Pack Size</b> | <b>Poison Schedule</b> |
|------------------|------------------------|

#### Components

##### 1 . Formulation 1

**Dosage Form** Capsule, hard

**Route of Administration** Oral

#### Visual Identification

#### Active Ingredients

|   |                 |
|---|-----------------|
| <b>Biota orientalis branch terminal leafy Extract dry concentrate</b> | <b>12.09 mg</b> |
| Equivalent: Biota orientalis (Dry)                                    | 72.54 mg        |
| <b>Citrus maxima fruit peel Extract dry concentrate</b>               | <b>12.09 mg</b> |
| Equivalent: Citrus maxima (Dry)                                       | 72.36 mg        |
| <b>Codonopsis pilosula root Extract dry concentrate</b>               | <b>21.78 mg</b> |
| Equivalent: Codonopsis pilosula (Dry)                                 | 130.68 mg       |
| <b>Cornus officinalis fruit Extract dry concentrate</b>               | <b>21.78 mg</b> |
| Equivalent: Cornus officinalis (Dry)                                  | 130.68 mg       |
| <b>Dioscorea oppositifolia rhizome Extract dry concentrate</b>        | <b>21.78 mg</b> |
| Equivalent: Dioscorea oppositifolia (Dry)                             | 130.68 mg       |
| <b>Epimedium brevicornu herb Extract dry concentrate</b>              | <b>21.78 mg</b> |
| Equivalent: Epimedium brevicornu (Dry)                                | 130.68 mg       |
| <b>Glycyrrhiza uralensis root Extract dry concentrate</b>             | <b>12.06 mg</b> |
| Equivalent: Glycyrrhiza uralensis (Dry)                               | 72.36 mg        |
| <b>Inula britannica flower Extract dry concentrate</b>                | <b>21.78 mg</b> |
| Equivalent: Inula britannica (Dry)                                    | 130.68 mg       |
| <b>Ophiopogon japonicus tuber Extract dry concentrate</b>             | <b>21.78 mg</b> |
| Equivalent: Ophiopogon japonicus (Dry)                                | 130.68 mg       |
| <b>Perilla frutescens seed Extract dry concentrate</b>                | <b>21.78 mg</b> |
| Equivalent: Perilla frutescens (Dry)                                  | 130.68 mg       |
| <b>Prunus armeniaca seed endosperm Extract dry concentrate</b>        | <b>21.78 mg</b> |
| Equivalent: Prunus armeniaca (Dry)                                    | 130.68 mg       |
| <b>Rehmannia glutinosa root Extract dry concentrate</b>               | <b>43.56 mg</b> |
| Equivalent: Rehmannia glutinosa (Dry)                                 | 261.36 mg       |
| <b>Wolfiporia cocos hyphae Extract dry concentrate</b>                | <b>21.78 mg</b> |
| Equivalent: Wolfiporia cocos (Dry)                                    | 130.68 mg       |
| <b>Ziziphus jujuba fruit Extract dry concentrate</b>                  | <b>24.18 mg</b> |
| Equivalent: Ziziphus jujuba (Dry)                                     | 145.08 mg       |

#### Other Ingredients (Excipients)

Agar

carrageenan

hypromellose

sodium citrate dihydrate

soluble maize starch

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