



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

## Public Summary

<b>Summary for ARTG Entry:</b>	171395	CLEAR THE PHLEGM FORMULA a.k.a. Wen Dan Tang
<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>	14/05/2010	
<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 . CLEAR THE PHLEGM FORMULA a.k.a. Wen Dan Tang

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	3/05/2018
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#### Permitted Indications

- Traditionally used in Chinese medicine to clear/drain heat in the gall bladder
- Traditionally used in Chinese medicine to regulate Qi
- Traditionally used in Chinese medicine to harmonise/soothe the stomach
- 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.
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to disease in any body organ.
- 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

For practitioner dispensing only.

#### Additional Product information



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**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>Citrus aurantium fruit Extract dry concentrate</b>	<b>39.72 mg</b>
Equivalent: Citrus aurantium (Dry)	238.32 mg
<b>Citrus reticulata fruit peel Extract dry concentrate</b>	<b>39.72 mg</b>
Equivalent: Citrus reticulata (Dry)	238.32 mg
<b>Glycyrrhiza uralensis root Extract dry concentrate</b>	<b>22.05 mg</b>
Equivalent: Glycyrrhiza uralensis (Dry)	132.3 mg
<b>Phyllostachys nigra stem wood Extract dry concentrate</b>	<b>52.95 mg</b>
Equivalent: Phyllostachys nigra (Dry)	317.7 mg
<b>Pinellia ternata tuber Extract dry concentrate</b>	<b>52.95 mg</b>
Equivalent: Pinellia ternata (Dry)	317.7 mg
<b>Wolfiporia cocos fruiting body Extract dry concentrate</b>	<b>39.72 mg</b>
Equivalent: Wolfiporia cocos (Dry)	238.32 mg
<b>Zingiber officinale rhizome Extract dry concentrate</b>	<b>13.23 mg</b>
Equivalent: Zingiber officinale (Dry)	79.38 mg
<b>Ziziphus jujuba fruit Extract dry concentrate</b>	<b>39.72 mg</b>
Equivalent: Ziziphus jujuba (Dry)	238.32 mg

**Other Ingredients (Excipients)**

**Agar**

**carrageenan**

**hypromellose**

**sodium citrate dihydrate**

**soluble maize starch**

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