Public Summary

Summary for ARTG Entry:	120481	Zhi Sou Hua Tan Te Xiao Fang A.K.A. Lonicera, Phragmites & Fritillaria Cough Clear 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	12/07/2005
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 . Zhi Sou Hua Tan Te Xiao Fang A.K.A. Lonicera, Phragmites & Fritillaria Cough Clear Formula

Product Type	Single Medicine Product	**Effective Date**	8/05/2018

Permitted Indications

Traditionally used in Chinese medicine to dispel/expel/extinguish/disperse/clear lung-heat in/of Lung Dampness - Phlegm Heat pattern

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

Traditionally used in Chinese medicine to clear/expel/dissolve/resolve Phlegm in/of Lung Dampness - Phlegm Heat pattern

Traditionally used in Chinese medicine to decrease/reduce/relieve cough

Indication Requirements

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

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.

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

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

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).

If coughing persists consult your doctor (or a healthcare professional) (or words to that effect).

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

forsythia suspensa fruit Extract dry concentrate	**34.5 mg**
Equivalent: forsythia suspensa (Dry)	207 mg
Fritillaria thunbergii bulb Extract dry concentrate	**26.1 mg**
Equivalent: Fritillaria thunbergii (Dry)	156.6 mg
Glycyrrhiza uralensis root Extract dry concentrate	**13.8 mg**
Equivalent: Glycyrrhiza uralensis (Dry)	82.8 mg
Lonicera japonica flower Extract dry concentrate	**43.2 mg**
Equivalent: Lonicera japonica (Dry)	259.2 mg
Magnolia liliflora flower bud Extract dry concentrate	**26.1 mg**
Equivalent: Magnolia liliflora (Dry)	156.6 mg
Mentha haplocalyx herb Extract dry concentrate	**26.1 mg**
Equivalent: Mentha haplocalyx (Dry)	156.6 mg
Peucedanum praeruptorum root Extract dry concentrate	**26.1 mg**
Equivalent: Peucedanum praeruptorum (Dry)	156.6 mg
Phragmites australis rhizome Extract dry concentrate	**34.5 mg**
Equivalent: Phragmites australis (Dry)	207 mg
Platycodon grandiflorus root Extract dry concentrate	**17.4 mg**
Equivalent: Platycodon grandiflorus (Dry)	104.4 mg
Prunus armeniaca seed Extract dry concentrate	**26.1 mg**
Equivalent: Prunus armeniaca (Dry)	156.6 mg
Scutellaria baicalensis root Extract dry concentrate	**26.1 mg**
Equivalent: Scutellaria baicalensis (Dry)	156.6 mg

Other Ingredients (Excipients)

hydrolysed gelatin

soluble maize starch

titanium dioxide

Public Summary