Public Summary

Summary for ARTG Entry:	174634 Qing Qi Hua Tan Zhi Ke Fang a.k.a. Cough Clear 2 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	7/08/2010
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 . Qing Qi Hua Tan Zhi Ke Fang a.k.a. Cough Clear 2 Formula

Product Type Single Medicine Product **Effective Date** 9/05/2018

Permitted Indications

Traditionally used in Chinese medicine to dispel/expel/extinguish/disperse/clear lung-heat

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

Indication Requirements

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

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.

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

Warnings

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

For practitioner dispensing only.

If coughing persists consult your doctor (or a healthcare professional) (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

Arctium lappa fruit Extract dry concentrate	**27 mg**
Equivalent: Arctium lappa (Dry)	162 mg
Biota orientalis branch terminal leafy Extract dry concentrate	**36 mg**
Equivalent: Biota orientalis (Dry)	216 mg
Fritillaria thunbergii bulb Extract dry concentrate	**36 mg**
Equivalent: Fritillaria thunbergii (Dry)	216 mg
Glycyrrhiza uralensis root Extract dry concentrate	**12 mg**
Equivalent: Glycyrrhiza uralensis (Dry)	72 mg
Houttuynia cordata herb Extract dry concentrate	**90 mg**
Equivalent: Houttuynia cordata (Dry)	540 mg
Platycodon grandiflorus root Extract dry concentrate	**18 mg**
Equivalent: Platycodon grandiflorus (Dry)	108 mg
Prunus armeniaca seed Extract dry concentrate	**36 mg**
Equivalent: Prunus armeniaca (Dry)	216 mg
Scutellaria baicalensis root Extract dry concentrate	**45 mg**
Equivalent: Scutellaria baicalensis (Dry)	270 mg

Other Ingredients (Excipients)

Agar
carrageenan
hypromellose
purified water
sodium citrate dihydrate
soluble maize starch