Public Summary

Summary for ARTG Entry:	352117 COUGH PLEX
ARTG entry for	Medicine Listed
Sponsor	The Pharmaceutical Plant Company Pty Ltd
Postal Address	3 Sigma Drive, Croydon South, VIC, 3136 Australia
ARTG Start Date	22/12/2020
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 . COUGH PLEX

Product Type Single Medicine Product **Effective Date** 22/12/2020

Permitted Indications

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common colds and flu

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common colds and flu in children over 2 years of age

Traditionally used in Western herbal medicine to expectorant/clear respiratory tract mucous

Traditionally used in Western herbal medicine to expectorant/clear respiratory tract mucous in children over 2 years of age

Traditionally used in Western herbal medicine to decrease/reduce/relieve mild bronchial cough

Traditionally used in Western herbal medicine to decrease/reduce/relieve mild bronchial cough in children over 2 years of age

Traditionally used in Western herbal medicine to decrease/reduce/relieve cough

Traditionally used in Western herbal medicine to decrease/reduce/relieve cough in children over 2 years of age

Indication Requirements

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

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

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

Product presentation must only refer to mild bronchitis.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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

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

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

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Contains ethanol or contains alcohol.

Additional Product information

Pack Size/Poison information	
Pack Size	**Poison Schedule**

Components

1 . Formulation 1

Dosage Form	Oral Liquid
Route of Administration	Oral
Visual Identification	

Active Ingredients

Glycyrrhiza glabra root Extract liquid	**100 microlitre/mL**
Equivalent: Glycyrrhiza glabra (Dry)	100 mg/mL
Marrubium vulgare leaf Extract liquid	**300 microlitre/mL**
Equivalent: Marrubium vulgare (Dry)	300 mg/mL
Sambucus nigra flower Extract liquid	**100 microlitre/mL**
Equivalent: Sambucus nigra (Dry)	100 mg/mL
Thymus vulgaris leaf Extract liquid	**80 microlitre/mL**
Equivalent: Thymus vulgaris (Dry)	80 mg/mL

Other Ingredients (Excipients)

Citrus limon
ethanol
glycerol
Pimpinella anisum
purified water