Public Summary

Summary for ARTG Entry:	271407 Ki Kids Cough & Cold Liquid
ARTG entry for	Medicine Listed
Sponsor	Martin & Pleasance Pty Ltd
Postal Address	PO Box 2007, SOUTH MELBOURNE, VIC, 3205 Australia
ARTG Start Date	25/02/2016
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 . Ki Kids Cough & Cold Liquid

Product Type Single Medicine Product **Effective Date** 22/01/2020

Permitted Indications

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

Traditionally used in Chinese medicine to expectorant/clear respiratory tract mucous

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common cold

Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of common cold

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

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

Traditionally used in Chinese medicine to enhance/improve/promote/increase cough productivity

Traditionally used in Western herbal medicine to enhance/improve/promote/increase cough productivity

Traditionally used in Chinese medicine to relieve symptoms of sore throat/pharyngitis

Indication Requirements

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

Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.

If symptoms persist consult your healthcare practitioner (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).

Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea [or words to that effect].

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	Oral Liquid
Route of Administration	Oral
Visual Identification	

Active Ingredients

Echinacea purpurea herb Juice concentrate	**4.444 mg/mL**
Equivalent: Echinacea purpurea (Fresh)	200 mg/mL
Glycyrrhiza glabra root Extract dry concentrate	**5.555 mg/mL**
Equivalent: Glycyrrhiza glabra (Dry)	50 mg/mL
Hedera helix leaf Extract dry concentrate	**1.25 mg/mL**
Equivalent: Hedera helix (Dry)	10 mg/mL
Lonicera japonica flower Extract dry concentrate	**10 mg/mL**
Equivalent: Lonicera japonica (Dry)	200 mg/mL

Other Ingredients (Excipients)

betadex
citric acid monohydrate
Flavour
glycerol
potassium sorbate
purified water
sodium hydroxide
sorbitol solution (70 per cent) (non-crystallising)