Public Summary

Summary for ARTG Entry:	286920 Ki Kids Chesty Roll-On
ARTG entry for	Medicine Listed
Sponsor	Martin & Pleasance Pty Ltd
Postal Address	PO Box 2007, SOUTH MELBOURNE, VIC, 3205 Australia
ARTG Start Date	20/03/2017
Product Category	Medicine
Status	Active
Approval Area	Listed Medicines

Conditions

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 Chesty Roll-On

Product Type Single Medicine Product **Effective Date** 28/08/2019

Permitted Indications

Traditionally used in European herbal medicine to decrease/reduce/relieve symptoms of common cold
- Linked indication - Decrease/reduce/relieve cough
- Linked indication - Decongestant/relieve nasal congestion
- Linked indication - Unblock/clear nasal passages
- Linked indication - Decrease/reduce/relieve mild upper respiratory tract congestion
- Linked indication - Decrease/reduce/relieve muscle pain/ache/soreness

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common cold
- Linked indication - Decrease/reduce/relieve muscle pain/ache/soreness
- Linked indication - Decongestant/relieve nasal congestion
- Linked indication - Unblock/clear nasal passages
- Linked indication - Decrease/reduce/relieve cough
- Linked indication - Decrease/reduce/relieve mild upper respiratory tract congestion

Indication Requirements

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

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.

Respiratory tract infections must be qualified by 'mild'.

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 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	Liniment
Route of Administration	Topical
Visual Identification	

Active Ingredients

Eucalyptus Oil	**100 mg/g**
Peppermint Oil	**50 mg/g**

Other Ingredients (Excipients)

Castor Oil

d-alpha-tocopheryl acetate