



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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| Summary for ARTG Entry: | 319746 | Oriental Botanicals Kids' Cough Fighter |
| ARTG entry for | Medicine Listed | |
| Sponsor | McPherson's Consumer Products Pty Ltd | |
| Postal Address | Locked Bag 5018, Kingsgrove, NSW, 2208 Australia | |
| ARTG Start Date | 4/07/2019 | |
| 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 . Oriental Botanicals Kids' Cough Fighter

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|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 31/07/2019 |
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Permitted Indications

- Traditionally used in Western herbal medicine to anti-inflammatory/relieve inflammation in children
- Traditionally used in Western herbal medicine to antispasmodic/spasmolytic in children
- Traditionally used in Western herbal medicine to decrease/reduce/relieve bronchial mucous congestion in children
- Traditionally used in Western herbal medicine to expectorant/clear respiratory tract mucous in children
- Traditionally used in Chinese medicine to decrease/reduce/relieve cough in children
- Traditionally used in Western herbal medicine to decrease/reduce/relieve cough in children
- Decrease/reduce/relieve cough in children

Indication Requirements

- Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.
- 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.

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).



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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.

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Oral Liquid, suspension

Route of Administration Oral

Visual Identification

Active Ingredients

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|--|--------------------|
| Glycyrrhiza uralensis root Extract dry concentrate | 13.25 mg/mL |
| Equivalent: Glycyrrhiza uralensis (Dry) | 53 mg/mL |
| Hedera helix leaf Extract dry concentrate | 2.544 mg/mL |
| Equivalent: Hedera helix (Dry) | 15.26 mg/mL |
| Inula helenium root Extract dry concentrate | 7.95 mg/mL |
| Equivalent: Inula helenium (Dry) | 79.5 mg/mL |
| Platycodon grandiflorus root Extract dry concentrate | 10.6 mg/mL |
| Equivalent: Platycodon grandiflorus (Dry) | 53 mg/mL |
| Thymus vulgaris flower and leaf Extract dry concentrate | 7.57 mg/mL |
| Equivalent: Thymus vulgaris (Dry) | 53 mg/mL |

Other Ingredients (Excipients)

citric acid

Flavour

glycerol

maltodextrin

potassium hydroxide

potassium sorbate

purified water

silicon dioxide

Stevia rebaudiana

xanthan gum

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