



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	321721 Kids' Cold & Flu 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	13/08/2019
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 . Kids' Cold & Flu Fighter

Product Type	Single Medicine Product	Effective Date	13/08/2019
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Permitted Indications

- Traditionally used in Chinese medicine to remove Heat toxin
- Traditionally used in Chinese medicine to dispel/expel/extinguish/disperse/clear wind-heat
- Traditionally used in Western herbal medicine to sudorific/diaphoretic/enhance/promote sweating/perspiration
- Traditionally used in Western herbal medicine to maintain/support immune system to fight illness
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of common colds and flu in/of externally contracted Wind-Heat pattern
 - Linked indication - Antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common colds and flu
 - Linked indication - Antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling
 - Linked indication - Decongestant/relieve nasal congestion
 - Linked indication - Unblock/clear nasal passages
 - Linked indication - Relieve runny/dripping nose
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common colds and flu
- Traditionally used in Chinese medicine to decrease/reduce/relieve chills associated with common cold in/of externally contracted Wind-Heat pattern
- Traditionally used in Chinese medicine to relieve symptoms of sore throat/pharyngitis in/of externally contracted Wind-Heat pattern
- Traditionally used in Western herbal 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).
- 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 only refer to detoxification in relation to natural body processes.

Public Summary



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Department of Health
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Label statement: Not to be used in children under 5 years.

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

Product presentation must not imply or refer to drugs/alcohol.

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

Product presentation must not imply or refer to serious immunological diseases.

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).

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
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Components

1 . Formulation 1

Dosage Form Oral Liquid, suspension

Route of Administration Oral

Visual Identification

Active Ingredients

Echinacea purpurea root and rhizome Extract dry concentrate	5.74 mg/mL
Equivalent: Echinacea purpurea (Dry)	34.44 mg/mL
forsythia suspensa fruit Extract dry concentrate	22.56 mg/mL
Equivalent: forsythia suspensa (Dry)	135.36 mg/mL
Lonicera japonica flower bud Extract dry concentrate	13.54 mg/mL
Equivalent: Lonicera japonica (Dry)	135.4 mg/mL
Sambucus nigra flower Extract dry concentrate	9.02 mg/mL
Equivalent: Sambucus nigra (Dry)	54.12 mg/mL
Sambucus nigra fruit Juice concentrate	13.6 mg/mL
Equivalent: Sambucus nigra (Fresh)	163.2 mg/mL

Other Ingredients (Excipients)

- citric acid
- dl-alpha-tocopheryl acetate
- Flavour
- glycerol
- maltodextrin
- potassium sorbate
- purified water
- silicon dioxide
- Stevia rebaudiana
- xanthan gum

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