



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 367670 Oriental Botanicals 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 1/06/2021

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 . Oriental Botanicals Kids' Cold & Flu Fighter

| Product Type | Single Medicine Product | Effective Date | 1/06/2021 |
|--------------|-------------------------|----------------|-----------|
|--------------|-------------------------|----------------|-----------|

Permitted Indications

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 Chinese medicine to antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling in/of externally contracted Wind-Heat pattern

Traditionally used in Western herbal medicine to antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling

Traditionally used in Western herbal medicine to maintain/support immune system to fight illness

Traditionally used in Chinese medicine to decrease/reduce/relieve headache symptoms in/of externally contracted Wind-Heat pattern

Traditionally used in Western herbal medicine to decongestant/relieve nasal congestion

Traditionally used in Western herbal medicine to unblock/clear nasal passages

Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of common colds and flu in/of externally contracted Wind-Heat pattern

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

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

Traditionally used in Chinese medicine to decrease/reduce/relieve chills associated with common cold in/of externally contracted Wind-Heat pattern

Traditionally used in Western herbal medicine to relieve runny/dripping nose

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

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

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

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

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: Not to be used in children under 5 years.

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.

Standard Indications

No Standard Indications included on Record



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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

Components

1 . Formulation 1

Dosage Form Oral Liquid

Route of Administration Oral

Visual Identification

Active Ingredients

| | |
|---|--------------------|
| Echinacea purpurea root Extract dry concentrate | 5.51 mg/mL |
| Equivalent: Echinacea purpurea (Dry) | 33.06 mg/mL |
| forsythia suspensa fruit Extract dry concentrate | 21.64 mg/mL |
| Equivalent: forsythia suspensa (Dry) | 129.84 mg/mL |
| Lonicera japonica flower Extract dry concentrate | 12.99 mg/mL |
| Equivalent: Lonicera japonica (Dry) | 129.9 mg/mL |
| Sambucus nigra fruit Juice concentrate | 13.05 mg/mL |
| Equivalent: Sambucus nigra (Fresh) | 156.6 mg/mL |
| Sambucus nigra flower Extract dry concentrate | 8.65 mg/mL |
| Equivalent: Sambucus nigra (Dry) | 51.9 mg/mL |

Other Ingredients (Excipients)

citric acid

d-alpha-tocopheryl acid succinate

Flavour

glycerol

maltodextrin

potassium sorbate

purified water

Stevia rebaudiana

xanthan gum

Public Summary

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