



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

|                                |   |                                |
|--------------------------------|---|--------------------------------|
| <b>Summary for ARTG Entry:</b> | 380598  | Oriental Botanicals Cold & Flu |
| <b>ARTG entry for</b>          | Medicine Listed                                     |                                |
| <b>Sponsor</b>                 | McPherson's Consumer Products Pty Ltd               |                                |
| <b>Postal Address</b>          | Locked Bag 5018, Kingsgrove, NSW, 2208<br>Australia |                                |
| <b>ARTG Start Date</b>         | 10/12/2021  |                                |
| <b>Product Category</b>        | Medicine  |                                |
| <b>Status</b>                  | Active  |                                |
| <b>Approval Area</b>           | 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 Cold & Flu

|                     |                         |                       |            |
|---------------------|-------------------------|-----------------------|------------|
| <b>Product Type</b> | Single Medicine Product | <b>Effective Date</b> | 10/12/2021 |
|---------------------|-------------------------|-----------------------|------------|

### Permitted Indications

Traditionally used in Chinese medicine to release Exterior

Traditionally used in Chinese medicine to disseminate/diffuse lungs/lung-qi

Traditionally used in Chinese medicine to dispel/expel/extinguish/disperse/clear exogenous wind

Traditionally used in Chinese medicine to dispel/expel/extinguish/disperse/clear wind-heat

Traditionally used in Chinese medicine to antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling in/of external Wind-cold attack pattern

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

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 maintain/support immune system to fight illness

Traditionally used in Chinese medicine to decrease/reduce/relieve headache symptoms in/of external Wind-cold attack pattern

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

Decrease/reduce/relieve common cold duration

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

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 symptoms of common colds and flu in/of externally contracted Wind-Heat pattern

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

Traditionally used in Chinese medicine to lung tonic/Enhance lung health

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 external Wind-cold attack pattern

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild tonsillitis

### Indication Requirements

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.



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

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

Product presentation must not imply or refer to disease in any body organ.

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 mild tonsillitis.

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).

#### Additional Product information

#### Pack Size/Poison information

##### Pack Size

##### Poison Schedule

#### Components

##### 1 . Formulation 1

**Dosage Form**                      Tablet, film coated  
**Route of Administration**      Oral

##### Visual Identification

#### Active Ingredients

|   |                  |
|---|------------------|
| <b>Echinacea purpurea root Extract dry concentrate</b>      | <b>156.25 mg</b> |
| Equivalent: Echinacea purpurea (Dry)                        | 937.5 mg         |
| <b>forsythia suspensa fruit Extract dry concentrate</b>     | <b>100 mg</b>    |
| Equivalent: forsythia suspensa (Dry)                        | 1.5 g            |
| <b>Lonicera japonica flower Extract dry concentrate</b>     | <b>30 mg</b>     |
| Equivalent: Lonicera japonica (Dry)                         | 300 mg           |
| <b>Platycodon grandiflorus root Extract dry concentrate</b> | <b>75 mg</b>     |
| Equivalent: Platycodon grandiflorus (Dry)                   | 750 mg           |
| <b>Schizonepeta tenuifolia herb Extract dry concentrate</b> | <b>75 mg</b>     |
| Equivalent: Schizonepeta tenuifolia (Dry)                   | 750 mg           |

#### Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate  
Carnauba Wax  
colloidal anhydrous silica  
croscarmellose sodium  
macrogol 4000  
magnesium stearate  
maltodextrin  
microcrystalline cellulose  
polysorbate 80  
polyvinyl alcohol  
purified talc

# Public Summary

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