



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	350168	Oriental Botanicals Cold & Flu
ARTG entry for	Medicine Listed	
Sponsor	McPherson's Consumer Products Pty Ltd	
Postal Address	Locked Bag 5018, Kingsgrove, NSW, 2208 Australia	
ARTG Start Date	30/11/2020	
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 Cold & Flu

Product Type	Single Medicine Product	Effective Date	30/11/2020
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Permitted Indications

Traditionally used in Western herbal medicine to maintain/support immune system to fight illness
 Traditionally used in Western herbal medicine to decrease/reduce/relieve common cold duration
 Decrease/reduce/relieve symptoms of common colds and flu
 Linked indication - Relieve weariness/tiredness/fatigue/feeling of weakness
 Linked indication - Antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling
 Linked indication - Decrease/reduce/relieve disturbed/restless sleep
 Linked indication - Decrease/reduce/relieve cough
 Linked indication - Relieve runny/dripping nose
 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 - Relieve runny/dripping nose
 Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common colds and flu
 Decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections
 Linked indication - Antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling
 Linked indication - Relieve runny/dripping nose
 Linked indication - Decrease/reduce/relieve cough
 Linked indication - Relieve weariness/tiredness/fatigue/feeling of weakness
 Linked indication - Decrease/reduce/relieve disturbed/restless sleep
 Relieve symptoms of sore throat/pharyngitis
 Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild tonsillitis

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.
 Product presentation must only refer to mild tonsillitis.
 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.
 Product presentation must not imply or refer to serious immunological diseases.
 Respiratory tract infections must be qualified by 'mild'.
 Product presentation must not imply or refer to chronic fatigue syndrome.
 Label statement: Not to be used in children under 5 years.

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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

Andrographis paniculata	33.93 mg
Echinacea purpurea root Extract dry concentrate	104.17 mg
Equivalent: Echinacea purpurea (Dry)	625 mg
forsythia suspensa fruit Extract dry concentrate	87.5 mg
Equivalent: forsythia suspensa (Dry)	525 mg
Isatis tinctoria root Extract dry concentrate	90 mg
Equivalent: Isatis tinctoria (Dry)	450 mg
Isatis tinctoria leaf Extract dry concentrate	90 mg
Equivalent: Isatis tinctoria (Dry)	450 mg
Lonicera japonica flower bud Extract dry concentrate	55 mg
Equivalent: Lonicera japonica (Dry)	550 mg
Magnolia liliflora flower bud Extract dry concentrate	58.33 mg
Equivalent: Magnolia liliflora (Dry)	350 mg
Platycodon grandiflorus root Extract dry concentrate	75 mg
Equivalent: Platycodon grandiflorus (Dry)	375 mg
Schizonepeta tenuifolia leaf Extract dry concentrate	60 mg
Equivalent: Schizonepeta tenuifolia (Dry)	300 mg

Other Ingredients (Excipients)

calcium carbonate
 calcium hydrogen phosphate
 Carnauba Wax
 colloidal anhydrous silica
 croscarmellose sodium
 hypromellose
 macrogol 400
 magnesium stearate
 maltodextrin
 microcrystalline cellulose

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