



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	340292	Bronchelix
ARTG entry for	Medicine Listed	
Sponsor	McPherson's Consumer Products Pty Ltd	
Postal Address	Locked Bag 5018, Kingsgrove, NSW, 2208 Australia	
ARTG Start Date	28/07/2020	
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.

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.

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 . Bronchelix

Product Type	Single Medicine Product	Effective Date	28/07/2020
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Permitted Indications

- Traditionally used in Chinese medicine to moisten lungs
- Traditionally used in Chinese medicine to disseminate/diffuse lungs/lung-qi
- Traditionally used in Chinese medicine to demulcent/soothe irritated tissues
- Traditionally used in Western herbal medicine to maintain/support immune system to fight illness
- Traditionally used in Western herbal medicine to antispasmodic/spasmodolytic
- Traditionally used in Chinese medicine to decrease/reduce/relieve mild bronchial irritation
- Traditionally used in Western herbal medicine to decrease/reduce/relieve bronchial mucous congestion
- Traditionally used in Chinese medicine to clear/expel/dissolve/resolve Phlegm
- Traditionally used in Chinese medicine to expectorant/clear respiratory tract mucous
- Traditionally used in Western herbal medicine to expectorant/clear respiratory tract mucous
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of common cold
- Linked indication - Decrease/reduce/relieve cough
- Traditionally used in Western herbal medicine to antitussive/cough suppressant
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild bronchial cough
- Traditionally used in Western herbal medicine to decrease/reduce/relieve cough
- Traditionally used in Chinese medicine to decrease/reduce/relieve cough
- Traditionally used in Western herbal medicine to relieve dry unproductive cough
- Traditionally used in Chinese medicine to relieve dry unproductive cough
- Traditionally used in Chinese medicine to maintain/support lung health
- Traditionally used in Chinese medicine to lung tonic/Enhance lung health
- Traditionally used in Western herbal medicine to lung tonic/Enhance lung health

Indication Requirements

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



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

Product presentation must only refer to mild bronchitis.

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

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

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 not imply or refer to serious musculoskeletal or neurological conditions.

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
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Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Aster tataricus root and rhizome Extract dry concentrate	60 mg
Equivalent: Aster tataricus (Dry)	300 mg
Glycyrrhiza uralensis root Extract dry concentrate	50 mg
Equivalent: Glycyrrhiza uralensis (Dry)	500 mg
Houttuynia cordata herb top Extract dry concentrate	30 mg
Equivalent: Houttuynia cordata (Dry)	300 mg
Inula helenium root Extract dry concentrate	187.5 mg
Equivalent: Inula helenium (Dry)	750 mg
Marrubium vulgare herb Extract dry concentrate	100 mg
Equivalent: Marrubium vulgare (Dry)	500 mg
Pinellia ternata tuber Extract dry concentrate	35 mg
Equivalent: Pinellia ternata (Dry)	350 mg
Platycodon grandiflorus root Extract dry concentrate	50 mg
Equivalent: Platycodon grandiflorus (Dry)	500 mg
Stemona sessilifolia root Extract dry concentrate	60 mg
Equivalent: Stemona sessilifolia (Dry)	300 mg
Thyme Oil	10 mg

Other Ingredients (Excipients)

- betadex
- colloidal anhydrous silica
- hypromellose
- magnesium stearate
- maltodextrin
- microcrystalline cellulose
- purified water

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