



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

## Public Summary

<b>Summary for ARTG Entry:</b>	340292	Bronchelix
<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 Australia	
<b>ARTG Start Date</b>	28/07/2020	
<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 . Bronchelix

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	28/06/2022
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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/spasmolytic
- 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 Western herbal medicine to expectorant/clear respiratory tract mucous
- Traditionally used in Chinese 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 Chinese medicine to decrease/reduce/relieve cough
- Traditionally used in Western herbal medicine to decrease/reduce/relieve cough
- Traditionally used in Chinese medicine to relieve dry unproductive cough
- Traditionally used in Western herbal 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: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

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

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

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.



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Product presentation must not imply or refer to serious immunological diseases.  
 Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.  
 Product presentation must only refer to mild bronchitis.  
 Product presentation must not imply or refer to disease in any body organ.

**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**

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

**Other Ingredients (Excipients)**

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

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