



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	347561	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	6/11/2020	
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 . Bronchelix

Product Type	Single Medicine Product	Effective Date	21/12/2020
---------------------	-------------------------	-----------------------	------------

Permitted Indications

- Traditionally used in Chinese medicine to moisten lungs
- Traditionally used in Western herbal medicine to demulcent/soothe irritated tissues
- Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
- 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 Western herbal medicine to decrease/reduce/relieve mild bronchial irritation
- Traditionally used in Chinese medicine to clear/expel/dissolve/resolve Phlegm
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild upper respiratory tract congestion
- Traditionally used in Western herbal medicine to expectorant/clear respiratory tract mucous
- Traditionally used in Western herbal 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 Western herbal medicine to relieve dry unproductive cough
- Traditionally used in Western herbal medicine to lung tonic/Enhance lung health
- Traditionally used in Chinese medicine to lung tonic/Enhance lung health
- Traditionally used in Chinese medicine to decrease/reduce/relieve throat irritation
- Traditionally used in Chinese 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.
- 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.
- Respiratory tract infections must be qualified by 'mild'.
- 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.

Public Summary



Australian Government
Department of Health
 Therapeutic Goods Administration

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 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).

If symptoms persist consult your healthcare practitioner (or words to that effect).

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).

Contains ethanol or contains alcohol.

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

Aster tataricus root and rhizome Extract liquid	50 mg/mL
Equivalent: Aster tataricus (Dry)	50 mg/mL
Glycyrrhiza uralensis root Extract liquid concentrate	12.5 mg/mL
Equivalent: Glycyrrhiza uralensis (Dry)	50 mg/mL
Houttuynia cordata herb Extract liquid	40 mg/mL
Equivalent: Houttuynia cordata (Dry)	40 mg/mL
Inula helenium root Extract liquid	100 mg/mL
Equivalent: Inula helenium (Dry)	100 mg/mL
Marrubium vulgare herb Extract liquid	85 mg/mL
Equivalent: Marrubium vulgare (Dry)	85 mg/mL
Platycodon grandiflorus root Extract liquid	45 mg/mL
Equivalent: Platycodon grandiflorus (Dry)	45 mg/mL
Stemona japonica root Extract liquid	40 mg/mL
Equivalent: Stemona japonica (Dry)	40 mg/mL
Thymus vulgaris herb Extract liquid	100 mg/mL
Equivalent: Thymus vulgaris (Dry)	100 mg/mL

Other Ingredients (Excipients)

- ethanol
- glycerol
- purified water
- Spearmint oil

Public Summary

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.