



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

## Public Summary

<b>Summary for ARTG Entry:</b>	142087	MediHerb Broncafect
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Integria Healthcare Australia Pty Ltd	
<b>Postal Address</b>	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
<b>ARTG Start Date</b>	12/07/2007	
<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 . MediHerb Broncafect

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	25/02/2021
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### Permitted Indications

- Traditionally used in Western herbal medicine to sudorific/diaphoretic/enhance/promote sweating/perspiration
- Traditionally used in Western herbal medicine to anti-inflammatory/relieve inflammation
- Traditionally used in Western herbal medicine to demulcent/soothe irritated tissues
- Traditionally used in Western herbal medicine to maintain/support immune system health
- Traditionally used in Western herbal medicine to helps enhance/improve/promote immune system function
- Traditionally used in Western herbal medicine to maintain/support healthy immune system function
- Traditionally used in Western herbal medicine to maintain/support immune system to fight illness
- Traditionally used in Western herbal medicine to helps stimulate a healthy immune system response
- Traditionally used in Western herbal medicine to antispasmodic/spasmolytic
- Traditionally used in Western herbal medicine to decrease/reduce/relieve bronchial mucous congestion
- Traditionally used in Western herbal medicine to decrease/reduce excess chest phlegm
- Traditionally used in Western herbal medicine to decrease/reduce excess mucous
- Traditionally used in Western herbal medicine to expectorant/clear respiratory tract mucous
- Traditionally used in Western herbal medicine to relieve symptoms of mild upper respiratory tract infections
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common cold
  - Linked indication - Relieve feelings of general malaise/general debility
  - Linked indication - Decrease/reduce/relieve mild upper respiratory tract congestion
  - Linked indication - Decrease/reduce/relieve throat mucous membrane irritation/inflammation
  - Linked indication - Decrease/reduce/relieve cough
  - Linked indication - Relieve runny/dripping nose
  - Linked indication - Decrease/reduce/relieve sneezing
- 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 Western herbal medicine to maintain/support lung health
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild throat infection

### 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 immunological diseases.

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 infections.

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 only refer to mild bronchitis.

Respiratory tract infections must be qualified by 'mild'.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Product presentation must not imply or refer to chronic fatigue syndrome.

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**

If coughing persists consult your doctor (or a healthcare professional) (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).

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**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

**Dosage Form**                      Tablet, film coated

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

<b>Asclepias tuberosa root Extract liquid</b>	<b>750 microlitre</b>
Equivalent: Asclepias tuberosa (Dry)	375 mg
<b>Echinacea purpurea root Extract liquid</b>	<b>750 microlitre</b>
Equivalent: Echinacea purpurea (Dry)	375 mg
<b>Glycyrrhiza glabra root Extract dry concentrate standardised</b>	<b>107.1 mg</b>
Equivalent: Glycyrrhiza glabra (Dry)	750 mg
<b>Marrubium vulgare herb Extract liquid</b>	<b>360 microlitre</b>
Equivalent: Marrubium vulgare (Dry)	180 mg
<b>Thyme Oil</b>	<b>10 mg</b>
<b>Zingiber officinale root Extract liquid concentrate</b>	<b>6 mg</b>
Equivalent: Zingiber officinale (Dry)	180 mg

**Other Ingredients (Excipients)**

- calcium hydrogen phosphate dihydrate
- colloidal anhydrous silica
- hypromellose
- magnesium stearate
- maltodextrin
- microcrystalline cellulose
- sodium starch glycollate

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