



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

## Public Summary

<b>Summary for ARTG Entry:</b>	325368	Mediherb Pulmaco
<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>	23/10/2019	
<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.

The Ginkgo biloba leaf extract used in the manufacture of this medicine must comply with the requirement of Identification Test B of the monograph Powdered Ginkgo Extract in the United States Pharmacopeia 32 - National Formulary 27 (USP32-NF27) as in force or existing from time to time. This condition does not apply to powdered or dried leaf.

### Products

#### 1 . Mediherb Pulmaco

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	28/01/2021
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#### Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Anti-inflammatory/relieve inflammation
- Traditionally used in Western herbal medicine to antispasmodic/spasmodic
- 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 mild bronchial cough

#### Indication Requirements

- 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.
- Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).
- Respiratory tract infections must be qualified by 'mild'.
- Product presentation must only refer to mild bronchitis.
- 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

- Use in children under 12 years is not recommended.
- Do not use if pregnant or likely to become pregnant (or words to that effect)
- If symptoms persist, seek the advice of a healthcare professional.



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Do not use while breastfeeding.  
For practitioner dispensing only.

**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**

<b>Curcuma longa rhizome Extract dry concentrate standardised</b>	<b>40 mg</b>
Equivalent: Curcuma longa (Dry)	1 g
<b>Fennel Oil</b>	<b>5 mg</b>
<b>Ginkgo biloba leaf Dry</b>	<b>20 mg</b>
Equivalent: Ginkgo biloba (Dry)	1000 mg
<b>Grindelia camporum herb Extract liquid</b>	<b>600 microlitre</b>
Equivalent: Grindelia camporum (Dry)	300 mg
<b>Justicia adhatoda leaf Extract dry concentrate</b>	<b>150 mg</b>
Equivalent: Justicia adhatoda (Dry)	750 mg
<b>Scutellaria baicalensis root Extract liquid</b>	<b>1 mL</b>
Equivalent: Scutellaria baicalensis (Dry)	500 mg

**Other Ingredients (Excipients)**

calcium hydrogen phosphate dihydrate  
colloidal anhydrous silica  
hypromellose  
magnesium stearate  
microcrystalline cellulose  
silicon dioxide  
sodium starch glycollate

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