



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	325368	Mediherb Pulmaco
ARTG entry for	Medicine Listed	
Sponsor	Integria Healthcare Australia Pty Ltd	
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
ARTG Start Date	23/10/2019	
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.

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

Product Type	Single Medicine Product	Effective Date	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

For practitioner dispensing only.

Use in children under 12 years is not recommended.

Do not use while breastfeeding.



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If symptoms persist, seek the advice of a healthcare professional.

Do not use if pregnant or likely to become pregnant (or words to that effect)

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

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