



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	355904	MediHerb Albizia Complex
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	1/03/2021	
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 . MediHerb Albizia Complex

Product Type	Single Medicine Product	Effective Date	30/04/2021
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Traditionally used in Chinese medicine to clear/dry/drain/eliminate/resolve dampness

Traditionally used in Chinese medicine to remove Heat toxin

Traditionally used in Ayurvedic medicine to helps decrease/reduce/relieve symptoms of mild allergies

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Linked indication - Unblock/clear nasal passages

Linked indication - Decrease/reduce/relieve sneezing

Linked indication - Helps decrease/reduce/relieve nasal itching

Linked indication - Relieve runny/dripping nose

Linked indication - Decrease/reduce/relieve skin irritation

Linked indication - Antipruritic/Relieves itchy skin

Traditionally used in Ayurvedic medicine to helps reduce occurrence of symptoms of mild allergies

Indication Requirements

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

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.

Product presentation must only refer to detoxification in relation to natural body processes.

Product presentation must not imply or refer to serious allergic conditions such as anaphylaxis.

Product presentation must not imply or refer to drugs/alcohol.

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

For practitioner dispensing only.

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



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

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

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

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

Albizia lebbek stem bark Extract dry concentrate	100 mg
Equivalent: Albizia lebbek (Dry)	800 mg
Nigella sativa seed Extract dry concentrate	100 mg
Equivalent: Nigella sativa (Dry)	500 mg
Scutellaria baicalensis root Extract dry concentrate	200 mg
Equivalent: Scutellaria baicalensis (Dry)	800 mg

Other Ingredients (Excipients)

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

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