



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	227092	Mediherb Astragalus 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	20/08/2014	
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 Astragalus Complex

Product Type	Single Medicine Product	Effective Date	3/03/2021
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Permitted Indications

- Aids/assists with recovery from illness/convalescence
- Maintain/support physical endurance/capacity/stamina
- Relieve weariness/tiredness/fatigue/feeling of weakness
- Maintain/support general health and wellbeing
- Maintain/support immune system health
- 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
- Maintain/support healthy immune system function
- Traditionally used in Western herbal medicine to maintain/support healthy immune system function
- Maintain/support immune system to fight illness
- 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
- Aids/assists the body to cope with environmental stress
- Support healthy stress response in the body
- Maintain/support mental endurance/stamina
- Traditionally used in Western herbal medicine to decrease/reduce/relieve the severity of common cold symptoms
 - Linked indication - Decrease/reduce/relieve throat mucous membrane irritation/inflammation
 - Linked indication - Relieve runny/dripping nose
 - Linked indication - Decrease/reduce/relieve cough
 - Linked indication - Decrease/reduce/relieve sneezing
 - Linked indication - Decrease/reduce/relieve mild upper respiratory tract congestion
 - Linked indication - Relieve feelings of general malaise/general debility
- Traditionally used in Western herbal medicine to relieve symptoms of mild upper respiratory tract infections
- Aids/assists with recovery from illness/convalescence
- Maintain/support physical endurance/capacity/stamina
- Relieve weariness/tiredness/fatigue/feeling of weakness
- Maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to maintain/support immune system health
- Maintain/support immune system health

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Traditionally used in Western herbal medicine to help enhance/improve/promote immune system function
Maintain/support healthy immune system function
Traditionally used in Western herbal medicine to maintain/support healthy immune system function
Maintain/support immune system to fight illness
Traditionally used in Western herbal medicine to maintain/support immune system to fight illness
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Linked indication - Decrease/reduce/relieve throat mucous membrane irritation/inflammation
Traditionally used in Western herbal medicine to relieve symptoms of mild upper respiratory tract infections

Indication Requirements

Product presentation must not imply or refer to chronic fatigue syndrome.
Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to mental illnesses, disorders or conditions.
Product presentation must not imply or refer to serious immunological diseases.
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 not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
Respiratory tract infections must be qualified by 'mild'.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

For practitioner dispensing only.
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).
If symptoms persist, seek the advice of a healthcare professional.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1. Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral

Visual Identification

Active Ingredients

Astragalus membranaceus root Extract liquid	1.7 mL
Equivalent: Astragalus membranaceus (Dry)	850 mg
Echinacea purpurea root Extract liquid	1.3 mL
Equivalent: Echinacea purpurea (Dry)	650 mg
Eleutherococcus senticosus root Extract dry concentrate standardised	75 mg
Equivalent: Eleutherococcus senticosus (Dry)	750 mg

Other Ingredients (Excipients)



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

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 colloidal anhydrous silica
 croscarmellose sodium
 hypromellose
 magnesium stearate
 microcrystalline cellulose
 sodium starch glycollate

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