



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

## Public Summary

<b>Summary for ARTG Entry:</b>	227817	Mediherb Andrographis Complex
<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>	11/09/2014	
<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 Andrographis Complex

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	19/02/2022
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### Permitted Indications

- Traditionally used in Western herbal medicine to alterative/blood cleanser/depurative/purifier
- Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to maintain/support immune system health
- 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
- Traditionally used in Western herbal medicine to maintain/support immune system to fight illness
- 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 decrease/reduce/relieve the severity of common cold symptoms
  - 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
  - Linked indication - Decrease/reduce/relieve cough
  - Linked indication - Decrease/reduce/relieve throat mucous membrane irritation/inflammation
  - Linked indication - Relieve runny/dripping nose
- Traditionally used in Western herbal medicine to decrease/reduce/relieve the severity of common cold symptoms
- 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.
- 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 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 disease in any body organ, in particular the kidney or liver.
- Product presentation must not imply or refer to serious immunological diseases.
- Product presentation must not imply or refer to drugs/alcohol.

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

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

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

Andrographis may cause taste disturbance including loss of taste. If you develop any adverse symptoms, stop use and seek medical advice (or words to that effect).

Andrographis may cause allergic reactions in some people. If you have a severe reaction (such as anaphylaxis), stop use and seek immediate medical attention (or words to that effect).

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).

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

#### 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>Andrographis paniculata leaf Extract dry concentrate standardised</b>	<b>142.9 mg</b>
Equivalent: Andrographis paniculata (Dry)	2000.6 mg
<b>Echinacea angustifolia root Extract liquid</b>	<b>400 microlitre</b>
Equivalent: Echinacea angustifolia (Dry)	200 mg
<b>Echinacea purpurea root Extract liquid</b>	<b>600 microlitre</b>
Equivalent: Echinacea purpurea (Dry)	300 mg
<b>Ocimum tenuiflorum herb Extract dry concentrate</b>	<b>100 mg</b>
Equivalent: Ocimum tenuiflorum (Dry)	500 mg
<b>Ocimum tenuiflorum herb Oil essential</b>	<b>10 mg</b>

##### Other Ingredients (Excipients)

calcium carbonate

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

hypromellose

magnesium stearate

maltodextrin

microcrystalline cellulose

sodium starch glycollate

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