



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	372874	MediHerb Sinus Forte
<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>	16/08/2021	
<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 Sinus Forte**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	16/08/2021
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**Permitted Indications**

- Traditionally used in Western herbal medicine to sudorific/diaphoretic/enhance/promote sweating/perspiration
- Traditionally used in Western herbal medicine to maintain/support body mucous membrane health
- Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to anti-inflammatory/relieve inflammation
- Traditionally used in Western herbal medicine to astringent/tightens tissues
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of hayfever
  - Linked indication - Decrease/reduce/relieve sneezing
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of allergic rhinitis
- 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
- 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
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common colds and flu
  - Linked indication - Relieve feelings of general malaise/general debility
  - 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
- Traditionally used in Western herbal medicine to decrease/reduce excess mucous
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild upper respiratory tract congestion
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of sinusitis
- Traditionally used in Western herbal medicine to relieve symptoms of mild upper respiratory tract infections
- Traditionally used in Western herbal medicine to maintain/support healthy mucous membranes/mucous tissue of the respiratory tract

**Indication Requirements**

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

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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.

Product presentation must not imply or refer to serious immunological diseases.

Respiratory tract infections must be qualified by 'mild'.

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

Product presentation must not imply or refer to chronic fatigue syndrome.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

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

For practitioner dispensing only.

Do not use if pregnant or likely to become pregnant (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).

**Additional Product information**

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

**Dosage Form**                      Tablet, film coated

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

<b>Capsicum annuum fruit Extract liquid</b>	<b>30 microlitre</b>
Equivalent: Capsicum annuum (Dry)	10 mg
<b>Echinacea purpurea root Extract liquid</b>	<b>740 microlitre</b>
Equivalent: Echinacea purpurea (Dry)	370 mg
<b>Euphrasia officinalis herb Extract liquid</b>	<b>1.3 mL</b>
Equivalent: Euphrasia officinalis (Dry)	650 mg
<b>hydrastis canadensis root and rhizome Extract dry concentrate</b>	<b>69.5 mg</b>
Equivalent: hydrastis canadensis (Dry)	125 mg
<b>Solidago virgaurea herb Extract liquid</b>	<b>1.3 mL</b>
Equivalent: Solidago virgaurea (Dry)	650 mg

**Other Ingredients (Excipients)**

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

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