



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:		372874	MediHerb Sinus Forte
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	16/08/2021		
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 Sinus Forte

Product Type	Single Medicine Product	Effective Date	16/01/2024
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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 mild upper respiratory tract congestion

Linked indication - Decrease/reduce/relieve sneezing

Linked indication - Decrease/reduce/relieve cough

Linked indication - Relieve runny/dripping nose

Linked indication - Decrease/reduce/relieve throat mucous membrane irritation/inflammation

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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Respiratory tract infections must be qualified by 'mild'.

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

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

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 chronic fatigue syndrome.

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).

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

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

For practitioner dispensing only.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Tablet, film coated
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Route of Administration	Oral
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Visual Identification

Active Ingredients

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