



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:		346624	MediHerb Echinacea Premium Tablets
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	27/10/2020		
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 Echinacea Premium Tablets

Product Type	Single Medicine Product	Effective Date	14/04/2025
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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
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
Traditionally used in Western herbal medicine to decrease/reduce/relieve the severity of common cold symptoms
Linked indication - Decrease/reduce/relieve cough
Linked indication - Decrease/reduce/relieve mild upper respiratory tract congestion
Linked indication - Relieve runny/dripping nose
Linked indication - Decrease/reduce/relieve throat mucous membrane irritation/inflammation
Linked indication - Decrease/reduce/relieve sneezing
Linked indication - Relieve feelings of general malaise/general debility
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 serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to chronic fatigue syndrome.
Product presentation must not imply or refer to mental illnesses, disorders or conditions.
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 only refer to detoxification in relation to natural body processes.
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 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

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

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).

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

Echinacea angustifolia root Extract liquid	1.2 mL
Equivalent: Echinacea angustifolia (Dry)	600 mg
Echinacea purpurea root Extract liquid	1.35 mL
Equivalent: Echinacea purpurea (Dry)	675 mg

Other Ingredients (Excipients)

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

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