



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	355156	Mediherb Elderberry
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	18/02/2021	
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 Elderberry

Product Type	Single Medicine Product	Effective Date	18/02/2021
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Helps reduce/decrease free radical damage to body cells

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common colds and flu in adults

Linked indication - Relieve runny/dripping nose

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

Linked indication - Sudorific/diaphoretic/enhance/promote sweating/perspiration

Linked indication - Decrease/reduce/relieve mild upper respiratory tract congestion

Linked indication - Decrease/reduce/relieve cough

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common colds and flu in children up to 12 years of age

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

Linked indication - Relieve runny/dripping nose

Linked indication - Decrease/reduce/relieve cough

Linked indication - Sudorific/diaphoretic/enhance/promote sweating/perspiration

Linked indication - Decrease/reduce/relieve mild upper respiratory tract congestion

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common colds and flu in children over 12 years of age

Linked indication - Relieve runny/dripping nose

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

Linked indication - Decrease/reduce/relieve cough

Linked indication - Sudorific/diaphoretic/enhance/promote sweating/perspiration

Linked indication - Decrease/reduce/relieve mild upper respiratory tract congestion

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common colds and flu in children over 5 years of age

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

Linked indication - Relieve runny/dripping nose

Linked indication - Decrease/reduce/relieve cough

Linked indication - Sudorific/diaphoretic/enhance/promote sweating/perspiration

Linked indication - Decrease/reduce/relieve mild upper respiratory tract congestion

Traditionally used in Western herbal medicine to relieve symptoms of mild upper respiratory tract infections in adults

Traditionally used in Western herbal medicine to relieve symptoms of mild upper respiratory tract infections in children over 5 years of age

Traditionally used in Western herbal medicine to relieve symptoms of mild upper respiratory tract infections in children over 12 years of age

Traditionally used in Western herbal medicine to relieve symptoms of mild upper respiratory tract infections in children up to 12 years of age

Indication Requirements

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).



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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

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

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Sambucus nigra fruit Juice concentrate	430 mg
Equivalent: Sambucus nigra (Fresh)	3.01 g

Other Ingredients (Excipients)

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

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