



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	332699	Eagle Elderberry Viral Protect
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	27/03/2020	
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 . Eagle Elderberry Viral Protect

Product Type	Single Medicine Product	Effective Date	25/02/2021
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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 sudorific/diaphoretic/enhance/promote sweating/perspiration
- Maintain/support general health and wellbeing
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support immune system to fight illness
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral) within normal range
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common colds and flu
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common colds and flu
 - Linked indication - Decrease/reduce/relieve mild upper respiratory tract congestion
 - Linked indication - Decrease/reduce/relieve sneezing
 - Linked indication - Decrease/reduce/relieve throat mucous membrane irritation/inflammation
 - Linked indication - Relieve runny/dripping nose
 - Linked indication - Decrease/reduce/relieve cough
- Traditionally used in Western herbal medicine to decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections
 - Linked indication - Decrease/reduce/relieve mild upper respiratory tract congestion
 - Linked indication - Decrease/reduce/relieve sneezing
 - Linked indication - Decrease/reduce/relieve throat mucous membrane irritation/inflammation
 - Linked indication - Relieve runny/dripping nose
 - Linked indication - Decrease/reduce/relieve cough
- 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 immunological diseases.
- 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).
- Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
- If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is

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inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

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

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

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

WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (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

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	120 mg
Sambucus nigra fruit Juice powder	333 mg
Equivalent: Sambucus nigra (Fresh)	2.33 g
zinc amino acid chelate	60 mg
Equivalent: zinc	12 mg

Other Ingredients (Excipients)

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

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