



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	332699	Eagle Elderberry Viral Protect
<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>	27/03/2020	
<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 . 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 cough
  - Linked indication - Relieve runny/dripping nose
  - Linked indication - Decrease/reduce/relieve throat mucous membrane irritation/inflammation
- 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.
- If product is indicated for supplementation, 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).
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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.

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.

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

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**

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