



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	355156	Mediherb Elderberry
<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>	18/02/2021	
<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 . 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 - 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 5 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 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**

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

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