



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	386656	Elderberry Echinacea & Olive Leaf
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Herbs of Gold Pty Ltd	
<b>Postal Address</b>	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
<b>ARTG Start Date</b>	3/04/2022 11:00:00 PM	
<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 . Elderberry Echinacea & Olive Leaf**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	4/04/2022
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**Permitted Indications**

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support general health and wellbeing
- Maintain/support general health and wellbeing in children
- Traditionally used in Western herbal medicine to antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling
- Traditionally used in Western herbal medicine to antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling in children
- Traditionally used in Western herbal medicine to maintain/support immune system health in children
- Traditionally used in Western herbal medicine to maintain/support immune system health
- Maintain/support immune system health
- Maintain/support healthy immune system function in children
- Traditionally used in Western herbal medicine to maintain/support healthy immune system function
- Maintain/support healthy immune system function
- Traditionally used in Western herbal medicine to maintain/support healthy immune system function
- Traditionally used in Western herbal medicine to maintain/support healthy immune system function in children
- Maintain/support immune system to fight illness in children
- Traditionally used in Western herbal medicine to maintain/support immune system to fight illness in children
- Traditionally used in Western herbal medicine to maintain/support immune system to fight illness
- Maintain/support immune system to fight illness
- 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 cough
- 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 in children
  - 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
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild upper respiratory tract congestion
- Traditionally used in Western herbal medicine to relieve symptoms of mild upper respiratory tract infections
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common cold in children

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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 cold in children  
 Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common cold  
 Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common cold  
 Linked indication - Decrease/reduce/relieve mild upper respiratory tract congestion  
 Linked indication - Decrease/reduce/relieve cough  
 Traditionally used in Western herbal medicine to relieve symptoms of sore throat/pharyngitis in children  
 Traditionally used in Western herbal medicine to relieve symptoms of sore throat/pharyngitis

**Indication Requirements**

Label statement: If symptoms persist, talk to your health professional.  
 Product presentation must not imply or refer to serious immunological diseases.  
 Label statement: Not to be used in children under 5 years.  
 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**

Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.  
 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**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

1 . Formulation 1

<b>Dosage Form</b>	Oral Liquid
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

<b>Echinacea angustifolia root Extract soft concentrate</b>	<b>12.5 mg/mL</b>
Equivalent: Echinacea angustifolia (Dry)	50 mg/mL
<b>Olea europaea leaf Extract liquid</b>	<b>100 mg/mL</b>
Equivalent: Olea europaea (Fresh)	100 mg/mL
<b>Sambucus nigra fruit flesh Juice concentrate</b>	<b>33.33 mg/mL</b>
Equivalent: Sambucus nigra (Fresh)	400 mg/mL

**Other Ingredients (Excipients)**

citric acid  
 Flavour  
 glycerol  
 potassium hydroxide  
 potassium sorbate  
 purified water  
 Stevia rebaudiana

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