



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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

Product Type	Single Medicine Product	Effective Date	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
Maintain/support immune system health
Traditionally used in Western herbal medicine to maintain/support immune system health
Traditionally used in Western herbal medicine to maintain/support immune system health in children
Traditionally used in Western herbal medicine to maintain/support healthy immune system function in children
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
Maintain/support immune system to fight illness
Traditionally used in Western herbal medicine to maintain/support immune system to fight illness
Traditionally used in Western herbal medicine to maintain/support immune system to fight illness in children
Maintain/support immune system to fight illness in children
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
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



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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 decrease/reduce/relieve symptoms of common cold 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 cold in children

Traditionally used in Western herbal medicine to relieve symptoms of sore throat/pharyngitis

Traditionally used in Western herbal medicine to relieve symptoms of sore throat/pharyngitis in children

Indication Requirements

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.

Label statement: If symptoms persist, talk to your health professional.

Respiratory tract infections must be qualified by 'mild'.

Product presentation must not imply or refer to serious immunological diseases.

Label statement: Not to be used in children under 5 years.

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

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Oral Liquid

Route of Administration Oral

Visual Identification

Active Ingredients

Echinacea angustifolia root Extract soft concentrate 12.5 mg/mL

Equivalent: Echinacea angustifolia (Dry) 50 mg/mL

Olea europaea leaf Extract liquid 100 mg/mL

Equivalent: Olea europaea (Fresh) 100 mg/mL

Sambucus nigra fruit flesh Juice concentrate 33.33 mg/mL

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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