



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

## Public Summary

<b>Summary for ARTG Entry:</b>	335157	Kiwiherb Echinature
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Phytomed Australia Pty Ltd	
<b>Postal Address</b>	GPO Box 4467, SYDNEY, NSW, 2001 Australia	
<b>ARTG Start Date</b>	25/04/2020	
<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 . Kiwiherb Echinature

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	12/04/2023
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#### Permitted Indications

- Traditionally used in Western herbal medicine to enhance/improve/promote immune defence/immunity
- Traditionally used in Western herbal medicine to helps enhance/improve/promote immune system function
- Traditionally used in Western herbal medicine to maintain/support immune system to fight illness
- 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

#### Indication Requirements

- Product presentation must not imply or refer to serious immunological diseases.
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
- Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

- Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).
- Not suitable for infants under the age of twelve months (or words to that effect).
- Contains ethanol or contains alcohol.
- (If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].
- If symptoms persist consult your healthcare practitioner (or words to that effect).

#### Additional Product information

#### Container information



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Type	Material	Life Time	Temperature	Closure	Conditions
Multiple containers	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

**Pack Size/Poison information**

Pack Size	Poison Schedule
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**Components**

**1 . Formulation 1**

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

**Visual Identification**

**Active Ingredients**

<b>Echinacea purpurea root Extract liquid standardised</b>	<b>800 microlitre/mL</b>
Equivalent: Echinacea purpurea (Dry)	400 mg/mL
<b>Glycyrrhiza glabra root Extract liquid</b>	<b>38 microlitre/mL</b>
Equivalent: Glycyrrhiza glabra (Dry)	38 mg/mL
<b>Honey</b>	<b>150 mg/mL</b>

**Other Ingredients (Excipients)**

Apple  
ethanol  
Flavour  
purified water

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