



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	335156	Kiwiherb Organic Cough Syrup
ARTG entry for	Medicine Listed	
Sponsor	Phytomed Australia Pty Ltd	
Postal Address	GPO Box 4467, SYDNEY, NSW, 2001 Australia	
ARTG Start Date	25/04/2020	
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 . Kiwiherb Organic Cough Syrup

Product Type	Single Medicine Product	Effective Date	17/04/2023
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Permitted Indications

Traditionally used in Western herbal medicine to expectorant/clear respiratory tract mucous

Traditionally used in Western herbal medicine to loosen respiratory tract mucous

Traditionally used in Western herbal medicine to decrease/reduce/relieve cough

Traditionally used in Western herbal medicine to maintain/support lung health

Traditionally used in Western herbal medicine to lung tonic/Enhance lung health

Indication Requirements

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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

(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).

Not suitable for infants under the age of twelve months (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).

If coughing persists consult your doctor (or a healthcare professional) (or words to that effect).

Contains ethanol or contains alcohol.

Additional Product information

Container information

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



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Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Liquids

Route of Administration Oral

Visual Identification

Active Ingredients

Althaea officinalis root Extract liquid	55 microlitre/mL
Equivalent: Althaea officinalis (Dry)	11 mg/mL
Honey	560 mg/mL
Inula helenium root Extract liquid	60 microlitre/mL
Equivalent: Inula helenium (Dry)	30 mg/mL
Marrubium vulgare herb Extract liquid	55 microlitre/mL
Equivalent: Marrubium vulgare (Dry)	27.5 mg/mL
Verbascum thapsus leaf Extract liquid	60 microlitre/mL
Equivalent: Verbascum thapsus (Dry)	30 mg/mL

Other Ingredients (Excipients)

Apple cider vinegar

Apple

ascorbic acid

Flavour

Lemon Oil

purified water

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