



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	382910	Manuka Zinc+ Lozenge
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	21/01/2022	
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 . Manuka Zinc+ Lozenge

Product Type	Effective Date
Single Medicine Product	21/01/2022

Permitted Indications

- Maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to soothe/relieve mouth/oral irritation
- Traditionally used in Western herbal medicine to demulcent/soothe irritated tissues
- Maintain/support smell sensation
- Maintain/support taste sensation
- Maintain/support immune system health
- Maintain/support immune system health in children over 5 years of age
- Maintain/support healthy immune system function in children over 5 years of age
- Maintain/support healthy immune system function
- Maintain/support immune system to fight illness in children over 5 years of age
- Maintain/support immune system to fight illness
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in children over 5 years of age
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in athletes
- Traditionally used in Western herbal medicine to decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections
- Traditionally used in Western herbal medicine to helps soothe respiratory tract
- Traditionally used in Western herbal medicine to antitussive/cough suppressant
- Traditionally used in Western herbal medicine to decrease/reduce/relieve cough
- Traditionally used in Western herbal medicine to relieve dry unproductive cough
- Traditionally used in Western herbal medicine to soothe respiratory tract mucous membranes/mucous tissue
- Traditionally used in Western herbal medicine to decrease/reduce/relieve throat irritation
- Traditionally used in Western herbal medicine to decrease/reduce/relieve throat mucous membrane irritation/inflammation
- Traditionally used in Western herbal medicine to relieve symptoms of sore throat/pharyngitis
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild tonsillitis

Indication Requirements



Australian Government
Department of Health
Therapeutic Goods Administration

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

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

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

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Respiratory tract infections must be qualified by 'mild'.

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 only refer to mild tonsillitis.

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].

Not suitable for infants under the age of twelve months (or words to that effect).

WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Lozenge

Route of Administration Oral

Visual Identification

Active Ingredients

Althaea officinalis root Extract dry concentrate	125 mg
Equivalent: Althaea officinalis (Dry)	500 mg
Honey	250 mg
Lemongrass Oil	5 mg
Lemon Oil	25 mg
zinc gluconate	97.66 mg
Equivalent: zinc	12.5 mg

Other Ingredients (Excipients)

colloidal anhydrous silica

dextrates

maltodextrin

pregelatinised rice starch

silicon dioxide

stearic acid

Stevia rebaudiana

thaumatin

Public Summary

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.