



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	247072	METAGENICS BRONCHO TONE
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Metagenics (Aust) Pty Ltd	
<b>Postal Address</b>	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
<b>ARTG Start Date</b>	10/07/2015	
<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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . METAGENICS BRONCHO TONE

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	7/05/2020
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#### Permitted Indications

Maintain/support immune system health  
Maintain/support healthy immune system function  
Decrease/reduce/relieve mild bronchial irritation  
Decrease/reduce/relieve bronchial mucous congestion  
Decrease/reduce/relieve symptoms of common colds and flu  
Traditionally used in Ayurvedic medicine to decrease/reduce excess mucous  
Helps soothe respiratory tract  
Traditionally used in Ayurvedic medicine to expectorant/clear respiratory tract mucous  
Relieve symptoms of mild upper respiratory tract infections  
Decrease/reduce/relieve symptoms of common cold  
Decrease/reduce/relieve mild bronchial cough  
Decrease/reduce/relieve cough

#### Indication Requirements

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.  
Product presentation must not imply or refer to serious immunological diseases.  
Label statement: If symptoms persist, talk to your health professional.  
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 bronchitis.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record



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**Warnings**

If coughing persists consult your doctor (or a healthcare professional) (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).  
 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).  
 If symptoms persist consult your healthcare practitioner (or words to that effect).  
 Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.  
 Andrographis may cause allergic reactions in some people. If you have a severe reaction (such as anaphylaxis), stop use and seek immediate medical attention (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**

**Dosage Form**                      Tablet, film coated  
**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

<b>Andrographis paniculata herb top Extract dry concentrate</b>	<b>30 mg</b>
Equivalent: Andrographis paniculata (Dry)	180 mg
<b>calcium ascorbate dihydrate</b>	<b>121.07 mg</b>
Equivalent: ascorbic acid	100 mg
<b>Citrus bioflavonoids extract</b>	<b>100 mg</b>
<b>Curcuma longa rhizome Extract dry concentrate</b>	<b>30 mg</b>
Equivalent: Curcuma longa (Dry)	180 mg
<b>cyanocobalamin</b>	<b>.2 mg</b>
<b>Eucalyptus globulus leaf Extract dry concentrate</b>	<b>60 mg</b>
Equivalent: Eucalyptus globulus (Dry)	360 mg
<b>Glycyrrhiza glabra root Extract dry concentrate</b>	<b>40 mg</b>
Equivalent: Glycyrrhiza glabra (Dry)	240 mg
<b>Justicia adhatoda leaf Extract dry concentrate</b>	<b>90 mg</b>
Equivalent: Justicia adhatoda (Dry)	540 mg
<b>Mentha arvensis leaf Extract dry concentrate</b>	<b>55 mg</b>
Equivalent: Mentha arvensis (Dry)	330 mg
<b>Ocimum tenuiflorum leaf Extract dry concentrate</b>	<b>35 mg</b>
Equivalent: Ocimum tenuiflorum (Dry)	210 mg
<b>Phyllanthus emblica fruit Extract dry concentrate</b>	<b>30 mg</b>
Equivalent: Phyllanthus emblica (Dry)	180 mg
<b>Picrorrhiza kurroa root Extract dry concentrate</b>	<b>35 mg</b>
Equivalent: Picrorrhiza kurroa (Dry)	210 mg
<b>Plectranthus barbatus root Extract dry concentrate</b>	<b>30 mg</b>
Equivalent: Plectranthus barbatus (Dry)	180 mg
<b>Withania somnifera root Extract dry concentrate</b>	<b>30 mg</b>
Equivalent: Withania somnifera (Dry)	180 mg
<b>zinc amino acid chelate</b>	<b>75 mg</b>
Equivalent: zinc	15 mg
<b>Zingiber officinale rhizome Extract dry concentrate</b>	<b>35 mg</b>
Equivalent: Zingiber officinale (Dry)	210 mg

**Other Ingredients (Excipients)**

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calcium hydrogen phosphate dihydrate  
citric acid  
colloidal anhydrous silica  
croscarmellose sodium  
hypolose  
hypromellose  
macrogol 8000  
magnesium stearate  
mannitol  
microcrystalline cellulose  
silicon dioxide  
soy polysaccharide

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