



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

## Public Summary

<b>Summary for ARTG Entry:</b>	302787	NC Lung Tonic
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Nutrition Care Pharmaceuticals Pty Ltd	
<b>Postal Address</b>	25-31 Keysborough Avenue, Keysborough, VIC, 3173 Australia	
<b>ARTG Start Date</b>	9/05/2018	
<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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 . NC Lung Tonic

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	24/01/2020
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### Permitted Indications

Maintain/support general health and wellbeing

Traditionally used in Western herbal medicine to demulcent/soothe irritated tissues

Traditionally used in Western herbal medicine to decrease/reduce/relieve bronchial mucous congestion

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common colds and flu

Traditionally used in Chinese medicine to decrease/reduce/relieve mild upper respiratory tract congestion

Traditionally used in Western herbal medicine to decrease/reduce/relieve mild upper respiratory tract congestion

Traditionally used in Chinese medicine to expectorant/clear respiratory tract mucous

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

Traditionally used in Ayurvedic medicine to decrease/reduce/relieve cough

Traditionally used in Chinese medicine to decrease/reduce/relieve cough

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

Traditionally used in Ayurvedic medicine to relieve hoarseness of voice

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

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

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

### 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).

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.



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**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

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

If symptoms persist consult your healthcare practitioner (or words to that effect).

(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].

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
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**Components**

**1 . Formulation 1**

**Dosage Form** Oral Liquid

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Glycyrrhiza glabra root Extract dry concentrate</b>	<b>5.715 mg/mL</b>
Equivalent: Glycyrrhiza glabra (Dry)	100 mg/mL
<b>Inula helenium root Extract dry concentrate</b>	<b>7.5 mg/mL</b>
Equivalent: Inula helenium (Dry)	75 mg/mL
<b>Verbascum thapsus leaf Extract dry concentrate</b>	<b>25 mg/mL</b>
Equivalent: Verbascum thapsus (Dry)	100 mg/mL
<b>Zingiber officinale root Extract dry concentrate</b>	<b>.5 mg/mL</b>
Equivalent: Zingiber officinale (Dry)	10 mg/mL

**Other Ingredients (Excipients)**

Acacia  
citric acid  
dextrin  
Eucalyptus Oil  
glycerol  
Honey  
maltodextrin  
menthol  
Peppermint Oil  
potassium sorbate  
purified water  
silicon dioxide  
Stevia rebaudiana  
xanthan gum

Public Summary

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