



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

## Public Summary

<b>Summary for ARTG Entry:</b>	281763	Phytaxil
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Biomedica Nutraceuticals Pty Ltd	
<b>Postal Address</b>	PO Box 7052, ALEXANDRIA, NSW, 2015 Australia	
<b>ARTG Start Date</b>	26/10/2016	
<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 . Phytaxil

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	2/11/2020
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### Permitted Indications

Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative  
Traditionally used in Western herbal medicine to vermifuge/helps remove intestinal threadworms/pinworms  
Traditionally used in Western herbal medicine to maintain/support digestive system health  
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia  
Traditionally used in Western herbal medicine to decongestant/relieve nasal congestion  
Traditionally used in Western herbal medicine to unblock/clear nasal passages  
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 expectorant/clear respiratory tract mucous  
Traditionally used in Western herbal medicine to decrease/reduce/relieve cough

### 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).  
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.  
  
Product presentation must not imply or refer to gastro oesophageal reflux disease.  
Product presentation must not imply or refer to other worms e.g. roundworm, tapeworm, hookworm.  
Respiratory tract infections must be qualified by 'mild'.

### 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).

### Additional Product information

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**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Capsule, hard

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Allium sativum bulb Extract dry</b>	<b>60 mg</b>
Equivalent: Allium sativum (Dry)	1.2 mg
<b>Commiphora myrrha gum oleoresin Extract dry concentrate</b>	<b>25 mg</b>
Equivalent: Commiphora myrrha (Dry)	250 mg
<b>Origanum vulgare twig leafy young Oil essential</b>	<b>50 mg</b>
<b>Phellodendron amurense stem bark Extract dry concentrate standardised</b>	<b>100 mg</b>
Equivalent: Phellodendron amurense (Dry)	2 g
<b>Thymus vulgaris leaf Extract dry concentrate</b>	<b>60 mg</b>
Equivalent: Thymus vulgaris (Dry)	600 mg

**Other Ingredients (Excipients)**

Acacia

colloidal anhydrous silica

disodium edetate

gellan gum

hydrochloric acid

hypromellose

maltodextrin

microcrystalline cellulose

potable water

potassium acetate

stearic acid

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