



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	364706	Allium Complex
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Bio-Practica Pty Ltd	
<b>Postal Address</b>	651 Portrush Road, GLEN OSMOND, SA, 5064 Australia	
<b>ARTG Start Date</b>	6/05/2021	
<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 . Allium Complex

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	6/05/2021
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### Permitted Indications

- Traditionally used in Ayurvedic medicine to anala mandya hara/increase in appetite
- Traditionally used in Ayurvedic medicine to atisara hara/ease diarrhoea
- Traditionally used in Ayurvedic medicine to anaha hara/anti flatulent
- Traditionally used in Ayurvedic medicine to krimighna (anthelmintic)/assists to expel thread worms
- Traditionally used in Western herbal medicine to sudorific/diaphoretic/enhance/promote sweating/perspiration
- Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to astringent/tightens tissues
- Traditionally used in Ayurvedic medicine to orexigenic/improve/promote healthy appetite
- Traditionally used in Chinese medicine to decrease/reduce/relieve diarrhoea
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve diarrhoea
- Traditionally used in Western herbal medicine to decrease/reduce/relieve diarrhoea
- Traditionally used in Chinese medicine to decrease/reduce/relieve diarrhoea in/of Damp-Heat pattern
- Traditionally used in Western herbal medicine to decrease/reduce/relieve colic (wind/gas pain)
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve flatulence/carminative
- Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
- Traditionally used in Ayurvedic medicine to maintain/support healthy digestive system function
- Traditionally used in Chinese medicine to decrease/reduce/relieve abdominal pain/discomfort
- Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal spasm
- Traditionally used in Western herbal medicine to antiemetic/Decrease/reduce/relieve vomiting
- Traditionally used in Western herbal medicine to decrease/reduce/relieve nausea
- Traditionally used in Western herbal medicine to expectorant/clear respiratory tract mucous

### Indication Requirements

- Product presentation must not imply or refer to gastro oesophageal reflux disease.
- If Ayurvedic terminology is used on medicine label, label statement: Talk to a Ayurvedic practitioner/health professional if you are unsure if this medicine is right for you.
- Label statement: If symptoms persist, talk to your health professional.

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Label statement: Seek medical advice if diarrhoea persists for more than: 6 hours in infants under 6 months, 12 hours in children under 3 years, 24 hours in children aged 3 to 6 years or 48 hours in adults and children over 6 years (or words to that effect).

Product presentation must not imply or refer to other worms e.g. roundworm, tapeworm, hookworm.

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 eating disorders.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

No Warnings included on Record

**Additional Product information**

**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form**                      Tablet, film coated

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

<b>Allium sativum bulb Extract dry concentrate</b>	<b>20 mg</b>
Equivalent: Allium sativum (Dry)	1 g
<b>Cinnamomum cassia stem bark Extract dry concentrate</b>	<b>37.5 mg</b>
Equivalent: Cinnamomum cassia (Dry)	750 mg
<b>Nigella sativa seed Extract dry concentrate</b>	<b>50 mg</b>
Equivalent: Nigella sativa (Dry)	1 g
<b>Origanum Oil Spanish</b>	<b>30 mg</b>
<b>Phellodendron amurense stem bark Extract dry concentrate</b>	<b>168.35 mg</b>
Equivalent: Phellodendron amurense (Dry)	3.367 g
<b>Punica granatum fruit peel Extract dry concentrate</b>	<b>40 mg</b>
Equivalent: Punica granatum (Dry)	2 g

**Other Ingredients (Excipients)**

calcium hydrogen phosphate dihydrate  
 Carnuba Wax  
 chlorophyllin-copper complex  
 colloidal anhydrous silica  
 croscarmellose sodium  
 crospovidone  
 hypromellose  
 macrogol 400  
 magnesium stearate  
 maltodextrin  
 microcrystalline cellulose  
 povidone  
 pregelatinised rice starch  
 rice starch

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