



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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

Product Type	Single Medicine Product	Effective Date	6/05/2021
---------------------	-------------------------	-----------------------	-----------

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 in/of Damp-Heat pattern
- Traditionally used in Western herbal medicine to decrease/reduce/relieve diarrhoea
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve diarrhoea
- Traditionally used in Chinese medicine to decrease/reduce/relieve diarrhoea
- 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

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).

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

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.



Australian Government
Department of Health
 Therapeutic Goods Administration

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

Product presentation must not imply or refer to gastro oesophageal reflux disease.

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

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

Other Ingredients (Excipients)

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

Public Summary



Australian Government

Department of Health
Therapeutic Goods Administration

© 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>.

Public Summary