



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	376611	IntestaSelect
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Bio Concepts Pty Ltd	
<b>Postal Address</b>	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
<b>ARTG Start Date</b>	20/10/2021	
<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 . IntestaSelect**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	30/06/2022
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**Permitted Indications**

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
- Traditionally used in Ayurvedic medicine to maintain/support general health and wellbeing
- Maintain/support general health and wellbeing
- Anti-inflammatory/relieve inflammation
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve loss of appetite
- Traditionally used in Ayurvedic medicine to maintain/support healthy appetite
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve diarrhoea
- Traditionally used in Ayurvedic medicine to decrease/reduce loose stools
- Traditionally used in Ayurvedic medicine to vermifuge/helps remove intestinal threadworms/pinworms
- Traditionally used in Western herbal medicine to vermifuge/helps remove intestinal threadworms/pinworms
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
  - Linked indication - Decrease/reduce/relieve flatulence/carminative
  - Linked indication - Decrease/reduce/relieve abdominal bloating/distention
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
  - Linked indication - Decrease/reduce/relieve flatulence/carminative
  - Linked indication - Decrease/reduce/relieve digestive spasms
  - Linked indication - Decrease/reduce/relieve abdominal bloating/distention
- Traditionally used in Western herbal medicine to relieve digestive discomfort
- Traditionally used in Ayurvedic medicine to relieve digestive discomfort
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support immune system to fight illness
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common colds and flu
- Traditionally used in Western herbal medicine to decrease/reduce excess mucous
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild upper respiratory tract congestion
- Traditionally used in Western herbal medicine to relieve symptoms of mild upper respiratory tract infections

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

**Indication Requirements**

Label statement: If symptoms persist, talk to your health professional.  
 Product presentation must not imply or refer to other worms e.g. roundworm, tapeworm, hookworm.  
 Product presentation must not imply or refer to serious immunological diseases.  
 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: 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 gastro oesophageal reflux disease.  
 Product presentation must not imply or refer to eating disorders.  
 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**

No Warnings included on Record

**Additional Product information**

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

<b>Dosage Form</b>	Capsule, modified release
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

<b>Allium sativum bulb Extract dry concentrate standardised</b>	<b>50 mg</b>
Equivalent: Allium sativum (Dry)	2.5 g
<b>Caraway Oil</b>	<b>100 mg</b>
<b>Nigella sativa seed Extract dry concentrate</b>	<b>100 mg</b>
Equivalent: Nigella sativa (Dry)	1000 mg
<b>Punica granatum fruit hull Extract dry concentrate</b>	<b>250 mg</b>
Equivalent: Punica granatum (Dry)	2.5 g
<b>Punica granatum fruit hull Extract dry concentrate</b>	<b>33.34 mg</b>
Equivalent: Punica granatum (Dry)	500 mg

**Other Ingredients (Excipients)**

colloidal anhydrous silica  
 gellan gum  
 hypromellose  
 microcrystalline cellulose  
 stearic acid

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