



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

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

Product Type	Effective Date
Single Medicine Product	30/06/2022

Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Traditionally used in Ayurvedic medicine to maintain/support general health and wellbeing
- Traditionally used in Western herbal 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

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, modified release

Route of Administration Oral

Visual Identification

Active Ingredients

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

Other Ingredients (Excipients)

colloidal anhydrous silica
 gellan gum
 hypromellose
 microcrystalline cellulose
 stearic acid

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