



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	211235	MediHerb Bacto-Cand GI
ARTG entry for	Medicine Listed	
Sponsor	Integria Healthcare Australia Pty Ltd	
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
ARTG Start Date	21/06/2013	
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 . MediHerb Bacto-Cand GI

Product Type	Single Medicine Product	Effective Date	14/06/2021
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Permitted Indications

- Traditionally used in Chinese medicine to clear/dry/drain/eliminate/resolve dampness
- Traditionally used in Chinese medicine to dispel/expel/disperse/clear internal/endogenous heat
- Traditionally used in Chinese medicine to remove Heat toxin
- Traditionally used in Ayurvedic medicine to maintain/support healthy appetite
- Traditionally used in Chinese medicine to decrease/reduce/relieve diarrhoea
- Traditionally used in Chinese medicine to decrease/reduce loose stools
- 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 Ayurvedic medicine to maintain/support healthy digestion
- Traditionally used in Ayurvedic medicine to maintain/support digestive system health
- Traditionally used in Ayurvedic medicine to maintain/support gastrointestinal system health
- Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal bloating/distention
- Traditionally used in Ayurvedic medicine to maintain/support healthy liver function
- Traditionally used in Ayurvedic medicine to maintain/support liver health

Indication Requirements

- Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
- Product presentation must not imply or refer to gastro oesophageal reflux disease.
- Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to eating disorders.
- 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 drugs/alcohol.
- If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.
- Product presentation must only refer to detoxification in relation to natural body processes.

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Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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 3-6 years or 48 hours in adults and children over 6 years, seek medical advice (or words to that effect).

Andrographis may cause allergic reactions in some people. If you have a severe reaction (such as anaphylaxis), stop use and seek immediate medical attention (or words to that effect).

If symptoms persist, seek the advice of a healthcare professional.

Do not use if pregnant or likely to become pregnant (or words to that effect)

For practitioner dispensing only.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Capsule, enteric

Route of Administration Oral

Visual Identification

Active Ingredients

Andrographis paniculata whole plant Extract dry concentrate standardised	100 mg
Equivalent: Andrographis paniculata (Dry)	1 g
Anise Oil	125 mg
Origanum vulgare leaf Oil essential	75 mg
Phellodendron amurense stem bark Extract dry concentrate standardised	80 mg
Equivalent: Phellodendron amurense (Dry)	1.6 g

Other Ingredients (Excipients)

Colour

ethylcellulose

Gelatin

glycerol

hydrochloric acid

lecithin

medium chain triglycerides

oleic acid

purified water

Rice bran oil

sodium alginate

stearic acid

strong ammonia solution

yellow beeswax

Public Summary

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