Public Summary

Summary for ARTG Entry:	315441 INNER HEALTH IBS CONTROL
ARTG entry for	Medicine Listed
Sponsor	Metagenics (Aust) Pty Ltd
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia
ARTG Start Date	15/03/2019
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . INNER HEALTH IBS CONTROL

Product Type Single Medicine Product **Effective Date** 15/03/2019

Permitted Indications

Decrease/reduce/relieve excess intestinal gas

Decrease/reduce/relieve flatulence/carminative

Relief of symptoms of medically diagnosed Irritable Bowel Syndrome

- Linked indication - Helps reduce occurrence of constipation
- Linked indication - Maintain/support bowel regularity
- Linked indication - Decrease/reduce/relieve abdominal bloating/distention
- Linked indication - Helps reduce occurrence of diarrhoea

Help reduce occurrence of symptoms of medically diagnosed Irritable Bowel Syndrome

Maintain/support healthy digestive system function

Maintain/support intestinal good/beneficial/friendly flora

Maintain/support gastrointestinal system health

Maintain/support healthy gastrointestinal function

Decrease/reduce/relieve abdominal pain/discomfort

Relieve digestive discomfort

Decrease/reduce/relieve gastrointestinal pain

Indication Requirements

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

Label statement: If symptoms persist or worsen talk to your medical practitioner.

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

Product presentation must only refer to medically diagnosed IBS.

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 for stimulant laxatives: Prolonged use may cause serious bowel problems.

Label statement: Do not use when abdominal pain, nausea or vomiting are present or if you develop diarrhoea. If you are pregnant or breastfeeding - seek the advice of a healthcare professional before taking this product (or words to that effect).

Product presentation must not refer to or imply weight loss.

Label statement: Drink plenty of water (or words to that effect).

Label statement: If symptoms persist, worsen or episodes become more frequent talk to your medical practitioner.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

Prolonged use may cause serious bowel problems.

Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product (or words to that effect).

Drink plenty of water (or words to that effect).

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).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral

Visual Identification

Active Ingredients

Bifidobacterium animalis ssp lactis	**1 billion organisms**
Lactobacillus acidophilus	**11 billion organisms**
Lactobacillus plantarum	**20 billion organisms**

Other Ingredients (Excipients)

dibasic potassium phosphate
disodium edetate
gellan gum
hypromellose
magnesium stearate
maltodextrin
microcrystalline cellulose
monobasic potassium phosphate
potable water
potassium acetate
silicon dioxide
sucrose

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