Public Summary

Summary for ARTG Entry:	346030 METAGENICS ULTRA FLORA GI SOOTHE
ARTG entry for	Medicine Listed
Sponsor	Metagenics (Aust) Pty Ltd
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia
ARTG Start Date	16/10/2020
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 . METAGENICS ULTRA FLORA GI SOOTHE

Product Type Single Medicine Product **Effective Date** 16/10/2020

Permitted Indications

Relief of symptoms of medically diagnosed Irritable Bowel Syndrome
Linked indication - Decrease/reduce/relieve abdominal pain/discomfort
Relief of symptoms of medically diagnosed Irritable Bowel Syndrome
Linked indication - Helps reduce occurrence of diarrhoea
Relief of symptoms of medically diagnosed Irritable Bowel Syndrome
Linked indication - Helps reduce occurrence of constipation
Relief of symptoms of medically diagnosed Irritable Bowel Syndrome
Linked indication - Decrease/reduce/relieve excess intestinal gas
Relief of symptoms of medically diagnosed Irritable Bowel Syndrome
Linked indication - Relieve digestive discomfort
Relief of symptoms of medically diagnosed Irritable Bowel Syndrome
Linked indication - Decrease/reduce/relieve abdominal bloating/distention
Relief of symptoms of medically diagnosed Irritable Bowel Syndrome
Linked indication - Decrease/reduce/relieve gastrointestinal pain
Relief of symptoms of medically diagnosed Irritable Bowel Syndrome
Relief of symptoms of medically diagnosed Irritable Bowel Syndrome
Linked indication - Decrease/reduce/relieve flatulence/carminative
Relief of symptoms of medically diagnosed Irritable Bowel Syndrome
Linked indication - Maintain/support bowel regularity
Help reduce occurrence of symptoms of medically diagnosed Irritable Bowel Syndrome
Maintain/support intestinal good/beneficial/friendly flora
Maintain/support gastrointestinal system health

Indication Requirements

Label statement: If symptoms persist or worsen talk to your medical practitioner.
Product presentation must only refer to medically diagnosed IBS.
Label statement: If symptoms persist, worsen or episodes become more frequent talk to your medical practitioner.
Product presentation must not imply or refer to gastro oesophageal reflux disease.
Label statement: If symptoms persist, talk to your health professional.
Label statement: Drink plenty of water (or words to that effect).

Product presentation must not refer to or imply weight loss.

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).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Prolonged use may cause serious bowel problems.

If symptoms persist consult your healthcare practitioner (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).

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).

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

Lactobacillus plantarum	**20 billion CFU**

Other Ingredients (Excipients)

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

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