



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	346033	INNER HEALTH IBS SUPPORT
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Metagenics (Aust) Pty Ltd	
<b>Postal Address</b>	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
<b>ARTG Start Date</b>	16/10/2020	
<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 . INNER HEALTH IBS SUPPORT**

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

- Relief of symptoms of medically diagnosed Irritable Bowel Syndrome  
Linked indication - Decrease/reduce/relieve colic (wind/gas pain)
- Relief of symptoms of medically diagnosed Irritable Bowel Syndrome  
Linked indication - Helps enhance/promote general health and wellbeing
- Relief of symptoms of medically diagnosed Irritable Bowel Syndrome  
Linked indication - Maintain/support healthy digestive system function
- Relief of symptoms of medically diagnosed Irritable Bowel Syndrome  
Linked indication - Enhance/promote healthy digestion
- Relief of symptoms of medically diagnosed Irritable Bowel Syndrome  
Linked indication - Maintain/support general health and wellbeing
- Relief of symptoms of medically diagnosed Irritable Bowel Syndrome  
Linked indication - Maintain/support healthy gastrointestinal function
- Relief of symptoms of medically diagnosed Irritable Bowel Syndrome  
Linked indication - Maintain/support healthy bowel/colon function
- Relief of symptoms of medically diagnosed Irritable Bowel Syndrome  
Linked indication - Helps enhance/promote healthy digestive system function
- Relief of symptoms of medically diagnosed Irritable Bowel Syndrome
- 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  
Linked indication - Decrease/reduce/relieve abdominal bloating/distention
- 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 - Decrease/reduce/relieve flatulence/carminative
- Relief of symptoms of medically diagnosed Irritable Bowel Syndrome  
Linked indication - Relieve digestive discomfort
- Help reduce occurrence of symptoms of medically diagnosed Irritable Bowel Syndrome
- Maintain/support intestinal good/beneficial/friendly flora in healthy adults

**Indication Requirements**



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

Product presentation must only refer to medically diagnosed IBS.

Label statement: If symptoms persist or worsen 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.

**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).

**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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