



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

## Public Summary

<b>Summary for ARTG Entry:</b>	295770	INNER HEALTH DIGESTIVE DEFENCE
<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>	1/11/2017	
<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.

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.

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 DIGESTIVE DEFENCE

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	30/07/2020
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### Permitted Indications

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

### Indication Requirements

Product presentation must not imply or refer to gastro oesophageal reflux disease.  
Product presentation must only refer to medically diagnosed IBS.  
Label statement: If symptoms persist or worsen talk to your medical practitioner.  
Label statement: If symptoms persist, talk to your health professional.  
Label statement: If symptoms persist, worsen or episodes become more frequent talk to your medical practitioner.

### Standard Indications

No Standard Indications included on Record

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**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**

**10 billion organisms**

**Other Ingredients (Excipients)**

**disodium edetate**

**gellan gum**

**hypromellose**

**magnesium stearate**

**maltodextrin**

**microcrystalline cellulose**

**potable water**

**potassium acetate**

**silicon dioxide**

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