



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	348334	GastroDaily
ARTG entry for	Medicine Listed	
Sponsor	Medlab Pty Ltd	
Postal Address	PO Box 6452, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	13/11/2020	
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 . GastroDaily

Product Type	Single Medicine Product	Effective Date	3/08/2021
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Permitted Indications

Maintain/support general health and wellbeing
Decrease/reduce/relieve bowel discomfort
Decrease/reduce/relieve diarrhoea
Relief of symptoms of medically diagnosed Irritable Bowel Syndrome
Maintain/support gastrointestinal system health
Maintain/support healthy gastrointestinal function
Decrease/reduce/relieve abdominal bloating/distention
Decrease/reduce/relieve abdominal cramping
Helps reduce occurrence of abdominal spasm
Maintain/support immune system health
Maintain/support healthy gastrointestinal immune function

Indication Requirements

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

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

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 only refer to medically diagnosed IBS.

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

Product presentation must not imply or refer to serious immunological diseases.

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



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adults and children over 6 years, seek medical advice (or words to that effect).
If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Multiple containers	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Powder
Route of Administration	Oral

Visual Identification

Active Ingredients

glutamine	333.33 mg/g
Larix arabinogalactan	333.33 mg/g
Saccharomyces cerevisiae (Boulardii)	41.667 mg/g

Other Ingredients (Excipients)

cocoa powder
colloidal anhydrous silica
Flavour
maltodextrin
Peppermint Oil
Stevia rebaudiana

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