



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	293856	Oriental Botanicals GutBiotic 60 Billion
ARTG entry for	Medicine Listed	
Sponsor	McPherson's Consumer Products Pty Ltd	
Postal Address	Locked Bag 5018, Kingsgrove, NSW, 2208 Australia	
ARTG Start Date	14/09/2017	
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 . Oriental Botanicals GutBiotic 60 Billion

Product Type	Single Medicine Product	Effective Date	26/10/2020
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Permitted Indications

Maintain/support general health and wellbeing in children
Decrease/reduce/relieve constipation
Decrease/reduce/relieve bowel discomfort
Decrease/reduce/relieve flatulence/carminative
Helps enhance/improve/promote/increase intestinal transit time
Maintain/support healthy digestive system function
Aid/assist digestion of lactose
Maintain/support digestive system health
Maintain/support intestinal good/beneficial/friendly flora in children
Maintain/support intestinal good/beneficial/friendly flora
Helps maintain/support good/beneficial/friendly gut flora during antibiotic use
Help restore good/beneficial/friendly gut flora after antibiotic use
Maintain/support gastrointestinal system health in children
Decrease/reduce/relieve abdominal bloating/distention
Maintain/support immune system health
Maintain/support healthy immune system function

Indication Requirements

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

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).

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

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

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

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

Product presentation must not refer to or imply weight loss.

Standard Indications



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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

Bifidobacterium breve	.5 billion CFU
Bifidobacterium lactis	14 billion CFU
Bifidobacterium lactis	4 billion CFU
Bifidobacterium longum	.5 billion CFU
Lactobacillus acidophilus	12 billion CFU
Lactobacillus casei	1.25 billion CFU
Lactobacillus delbrueckii ssp bulgaricus	.1 billion CFU
Lactobacillus gasseri	.1 billion CFU
Lactobacillus paracasei	14.8 billion CFU
Lactobacillus plantarum	7 billion CFU
Lactobacillus rhamnosus	2 billion CFU
Lactobacillus rhamnosus	2 billion CFU
Lactobacillus salivarius ssp salivarius	1.25 billion CFU
Streptococcus thermophilus	.5 billion CFU

Other Ingredients (Excipients)

colloidal anhydrous silica
 gellan gum
 hypromellose
 magnesium stearate
 microcrystalline cellulose

Public Summary

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