Australian Government

Department of Health
Therapeutic Goods Administration

# Public Summary

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|---|---|
| **Summary for ARTG Entry:** | 336058 ENBIOTIC |
| **ARTG entry for** | Medicine Listed |
| **Sponsor** | Medlab Pty Ltd |
| **Postal Address** | PO Box 6452, ALEXANDRIA, NSW, 2015 Australia |
| **ARTG Start Date** | 8/05/2020 |
| **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 . ENBIOTIC

**Product Type** Single Medicine Product **Effective Date** 12/07/2021

#### Permitted Indications

Decrease/reduce/relieve bowel discomfort
Helps enhance/promote healthy digestive system function
Maintain/support healthy digestive system function
Enhance/promote healthy digestion
Maintain/support healthy digestion
Maintain/support digestion/assimilation of nutrients
Aid/assist digestion/breakdown of dietary fat
Aid/assist/helps digestion of fats/fatty acids/triglycerides/lipid
Aid/assist digestion of glucose/sugar/carbohydrates
Aid/assist/helps digestion of (state nutrient)
Maintain/support digestive system health
Helps restore good/beneficial/friendly intestinal/gut/bowel flora
Decrease/reduce/relieve abdominal bloating/distention
Decrease/reduce/relieve abdominal pain/discomfort
Maintain/support healthy immune system function

#### Indication Requirements

Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.

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

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

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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 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 |
|---|---|

## Components

### 1 . Formulation 1

**Dosage Form** Capsule, hard

**Route of Administration** Oral

**Visual Identification**

#### Active Ingredients

| | |
|---|---|
| **Amylase** | **750 DU** |
| **Bifidobacterium animalis ssp lactis** | **1.125 billion CFU** |
| **Bifidobacterium bifidum** | **125 million CFU** |
| **bromelains** | **.2178 million PU** |
| **Lactobacillus acidophilus** | **5 billion CFU** |
| **Lactobacillus rhamnosus** | **2.5 billion CFU** |
| **lipase** | **525 LipU** |
| **papain** | **.2352 million PU** |
| **protease** | **3.79 Thousand HUT** |

#### Other Ingredients (Excipients)

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

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