



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	370142	SporeBiotic
ARTG entry for	Medicine Listed	
Sponsor	Spectrumceuticals Pty Ltd	
Postal Address	10/5 Narabang Way, BELROSE, NSW, 2085 Australia	
ARTG Start Date	24/06/2021	
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 . SporeBiotic

Product Type	Single Medicine Product	Effective Date	28/06/2021
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Permitted Indications

Maintain/support general health and wellbeing
Maintain/support bowel regularity
Decrease/reduce/relieve bowel discomfort in healthy adults
Maintain/support healthy bowel/colon function
Maintain/support intestinal health
Maintain/support intestinal good/beneficial/friendly flora
Maintain/support gastrointestinal system health

Indication Requirements

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: If symptoms persist, talk to your health professional.

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

Product presentation must not refer to or imply weight loss.

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Bacillus coagulans may affect the way some medicines work, including immunosuppressants. Consult your health professional before taking with other medicines (or words to that effect)

If symptoms persist consult your healthcare practitioner (or words to that effect).

Not suitable for children.

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

Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a



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healthcare professional before taking this product (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

Bacillus coagulans	2 billion CFU
fructooligosaccharides	100 mg
Saccharomyces cerevisiae (Boulardii)	250 mg

Other Ingredients (Excipients)

colloidal anhydrous silica
hypromellose
magnesium stearate
maltodextrin
microcrystalline cellulose
purified water

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