



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	398788	UltraBiotic 500
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
ARTG Start Date	2/11/2022	
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 . UltraBiotic 500

Product Type	Single Medicine Product	Effective Date	2/11/2022
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Permitted Indications

Maintain/support bowel regularity
Decrease/reduce/relieve bowel discomfort
Maintain/support healthy digestive system function
Maintain/support healthy digestion
Aid/assist digestion of lactose
Maintain/support digestive system health
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
Decrease/reduce/relieve abdominal bloating/distention
Relieve digestive discomfort
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support healthy gastrointestinal immune function

Indication Requirements

Label statement for stimulant laxatives: Prolonged use may cause serious bowel problems.
Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to serious immunological diseases.
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).
Product presentation must not refer to or imply weight loss.

Product presentation must not imply or refer to gastro oesophageal reflux disease.
Label statement: Drink plenty of water (or words to that effect).

Standard Indications

No Standard Indications included on Record



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Specific Indications	
No Specific Indications included on Record	
Warnings	
(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].	
Additional Product information	
Pack Size/Poison information	
Pack Size	Poison Schedule
Components	
1 . Formulation 1	
Dosage Form	Powder, oral
Route of Administration	Oral
Visual Identification	
Active Ingredients	
Bifidobacterium animalis ssp lactis	51 billion CFU/g
Bifidobacterium bifidum	1 billion CFU/g
Bifidobacterium longum	1 billion CFU/g
Lactobacillus acidophilus	10 billion CFU/g
Lactobacillus brevis	3 billion CFU/g
Lactobacillus casei	2 billion CFU/g
Lactobacillus gasseri	3 billion CFU/g
Lactobacillus paracasei	10 billion CFU/g
Lactobacillus plantarum	6 billion CFU/g
Lactobacillus rhamnosus	3 billion CFU/g
Lactobacillus salivarius ssp salivarius	8 billion CFU/g
Streptococcus thermophilus	2 billion CFU/g
Other Ingredients (Excipients)	
Acacia	
calcium silicate	
dibasic potassium phosphate	
glucose monohydrate	
maize starch	
maltodextrin	
monobasic potassium phosphate	
sodium ascorbate	
sodium chloride	
sucrose	
trehalose dihydrate	

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