



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	305256	UB NuroBiota
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	26/06/2018	
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 . UB NuroBiota

Product Type	Single Medicine Product	Effective Date	12/10/2021
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Permitted Indications

Maintain/support digestive system health
Maintain/support intestinal good/beneficial/friendly flora
Maintain/support healthy immune system function
Maintain/support healthy gastrointestinal immune function
Help maintain/support emotional wellbeing
Support healthy emotional/mood balance

Indication Requirements

Product presentation must not imply or refer to serious immunological diseases.
Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral

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Visual Identification

Active Ingredients

Bifidobacterium bifidum	2 billion CFU
Bifidobacterium lactis	1 billion CFU
Bifidobacterium longum	1 billion CFU
Lactobacillus acidophilus	2 billion CFU
Lactobacillus casei	2 billion CFU
Lactobacillus helveticus	2 billion CFU
Lactobacillus plantarum	1 billion CFU
Lactobacillus rhamnosus	1 billion CFU

Other Ingredients (Excipients)

colloidal anhydrous silica
hypromellose
magnesium stearate
microcrystalline cellulose
potable water

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