



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:		305256	UB NuroBiota
ARTG entry for	Medicine Listed		
Sponsor	FIT-BioCeuticals Pty Ltd		
Postal Address	Level 4 / 64 Kippax Street, Surry Hills, NSW, 2010 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	11/09/2025
---------------------	-------------------------	-----------------------	------------

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
------------------	------------------------

Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral



Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

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	

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary