



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	363824	METAGENICS ULTRA FLORA NEURO SUPPORT
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Metagenics (Aust) Pty Ltd	
<b>Postal Address</b>	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
<b>ARTG Start Date</b>	30/04/2021	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 . METAGENICS ULTRA FLORA NEURO SUPPORT

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	30/04/2021
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#### Permitted Indications

Maintain/support general health and wellbeing  
Maintain/support healthy bowel/colon function  
Maintain/support healthy digestion  
Maintain/support digestive system health  
Maintain/support intestinal good/beneficial/friendly flora  
Maintain/support gastrointestinal system health  
Maintain/support healthy gastrointestinal function  
Support healthy stress response in the body  
Help maintain/support emotional wellbeing  
Maintain/support general mental wellbeing  
Maintain/support brain function  
Maintain/support neuroendocrine function  
Support healthy emotional/mood balance

#### Indication Requirements

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

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

#### Additional Product information

#### Pack Size/Poison information



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Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Lactobacillus paracasei 8.75 billion CFU

Lactobacillus plantarum 10 billion CFU

Other Ingredients (Excipients)

dibasic potassium phosphate

disodium edetate

gellan gum

hypromellose

magnesium stearate

maltodextrin

microcrystalline cellulose

potable water

potassium acetate

silicon dioxide

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Public Summary