



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	318836	METAGENICS ULTRA FLORA BABY CARE
<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>	12/06/2019	
<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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 BABY CARE

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	12/06/2019
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#### Permitted Indications

- Maintain/support digestive system health in healthy infants
- Maintain/support digestive system health in children
- Maintain/support intestinal good/beneficial/friendly flora in children
- Maintain/support intestinal good/beneficial/friendly flora in healthy infants
- Helps maintain/support good/beneficial/friendly gut flora during antibiotic use in children
- Helps maintain/support good/beneficial/friendly gut flora during antibiotic use in healthy infants
- Help restore good/beneficial/friendly gut flora after antibiotic use in healthy infants
- Help restore good/beneficial/friendly gut flora after antibiotic use in children
- Helps restore good/beneficial/friendly intestinal/gut/bowel flora in healthy infants
- Helps restore good/beneficial/friendly intestinal/gut/bowel flora in children
- Maintain/support healthy immune system function in children
- Maintain/support healthy immune system function in healthy infants

#### Indication Requirements

Product presentation must not imply or refer to serious immunological diseases.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record



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**Warnings**

If symptoms persist consult your healthcare practitioner (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**

<b>Bifidobacterium animalis ssp lactis</b>	<b>3.57 billion organisms/g</b>
<b>Bifidobacterium breve</b>	<b>1.79 billion organisms/g</b>
<b>Bifidobacterium longum</b>	<b>1.79 billion organisms/g</b>
<b>Lactobacillus rhamnosus</b>	<b>4.29 billion organisms/g</b>

**Other Ingredients (Excipients)**

calcium phosphate

glucose

maltodextrin

sodium ascorbate

sucrose

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