



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	320944	METAGENICS ULTRA FLORA KIDS CARE
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	29/07/2019	
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.

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 KIDS CARE

Product Type	Effective Date
Single Medicine Product	29/07/2019

Permitted Indications

- Decrease/reduce/relieve diarrhoea in children
- Maintain/support healthy bowel/colon function 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
- Help restore good/beneficial/friendly gut flora after antibiotic use in children
- Helps restore good/beneficial/friendly intestinal/gut/bowel flora in children
- Maintain/support gastrointestinal system health in children
- Maintain/support healthy immune system function in children
- Decrease/reduce/relieve symptoms of mild eczema/dermatitis in healthy infants

Indication Requirements

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

Label statement: Seek medical advice if diarrhoea persists for more than: 6 hours in infants under 6 months, 12 hours in children under 3 years, 24 hours in children aged 3 to 6 years or 48 hours in adults and children over 6 years (or words to that effect).

Product presentation must only refer to mild eczema.

Label statement: If symptoms persist, talk to your health professional.

Standard Indications

No Standard Indications included on Record

Public Summary



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Department of Health
Therapeutic Goods Administration

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].

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

If diarrhoea persists for more than 6 hours in infants under 6 months, 12 hours in children under 3 years, 24 hours in children aged 3-6 years or 48 hours in adults and children over 6 years, seek medical advice (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 lactis	1.25 billion organisms/g
fructooligosaccharides	500 mg/g
Lactobacillus acidophilus	1.25 billion organisms/g
Lactobacillus rhamnosus	3 billion organisms/g

Other Ingredients (Excipients)

fructose

glucose

maltodextrin

sodium ascorbate

sucrose

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