

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 286746 METAGENICS ULTRA FLORA INTENSIVE CARE

ARTG entry for Medicine Listed

Sponsor Metagenics (Aust) Pty Ltd

Postal Address PO Box 675, VIRGINIA BC, QLD, 4014

Australia

ARTG Start Date 15/03/2017

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.

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 INTENSIVE CARE

Product Type Single Medicine Product Effective Date 4/08/2020

Permitted Indications

Helps reduce occurrence of diarrhoea

Maintain/support healthy bowel/colon function

Maintain/support healthy digestive system function

Maintain/support healthy mucous linings of the digestive system

Maintain/support digestive system health

Maintain/support intestinal good/beneficial/friendly flora

Helps maintain/support good/beneficial/friendly gut flora during antibiotic use

Help restore good/beneficial/friendly gut flora after antibiotic use

Helps restore good/beneficial/friendly intestinal/gut/bowel flora

Maintain/support gastrointestinal system health

Maintain/support healthy gastrointestinal function

Maintain/support gastrointestinal mucosal membrane health

Indication Requirements

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).

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).

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Additional Product information

Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification
Active Ingredients

Bifidobacterium animalis ssp lactis 5 billion CFU
Lactobacillus rhamnosus 10 billion CFU
Saccharomyces cerevisiae (Boulardii) 7.5 billion CFU

Other Ingredients (Excipients)

disodium edetate

gellan gum

hypromellose

magnesium stearate

maltodextrin

potable water

potassium acetate

silicon dioxide

sodium ascorbate sorbitan monostearate

sucrose

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