



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 329302 METAGENICS ULTRA FLORA RESTORE DAIRY FREE

ARTG entry for Medicine Listed
Sponsor Metagenics (Aust) Pty Ltd
Postal Address PO Box 675, VIRGINIA BC, QLD, 4014
Australia
ARTG Start Date 31/01/2020
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 RESTORE DAIRY FREE

| Product Type | Effective Date |
|-------------------------|----------------|
| Single Medicine Product | 31/01/2020 |

Permitted Indications

Traditionally used in Eclectic medicine to trophorestorative/restore organ health
Maintain/support general health and wellbeing
Maintain/support body tissue repair/regeneration
Maintain/support healthy digestive system function
Maintain/support healthy digestion
Maintain/support digestive system health
Maintain/support intestinal good/beneficial/friendly flora
Helps enhance/improve/promote/increase healthy digestive system flora/good bacteria growth
Maintain/support gastrointestinal system health
Maintain/support immune system health in children
Maintain/support immune system health
Maintain/support healthy immune system function in children
Maintain/support healthy immune system function
Maintain/support healthy gastrointestinal immune function in children
Maintain/support healthy gastrointestinal immune function

Indication Requirements

Product presentation must not imply or refer to disease in any body organ.
Product presentation must not imply or refer to serious immunological diseases.

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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

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

| | |
|----------------------------------|-------------------------------|
| Bifidobacterium lactis | 11.5 billion organisms |
| Lactobacillus acidophilus | 11.5 billion organisms |
| Lactobacillus rhamnosus | 2 billion organisms |

Other Ingredients (Excipients)

disodium edetate
gellan gum
hypromellose
magnesium stearate
maltodextrin
potable water
potassium acetate
silicon dioxide
sodium ascorbate
sucrose

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