



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

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|--------------------------------|---|----------------------------|
| Summary for ARTG Entry: | 215859 | Inner Health Gastro Relief |
| ARTG entry for | Medicine Listed | |
| Sponsor | Metagenics (Aust) Pty Ltd | |
| Postal Address | PO Box 675, VIRGINIA BC, QLD, 4014 Australia | |
| ARTG Start Date | 10/10/2013 | |
| 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 . Inner Health Gastro Relief

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 10/09/2020 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

- Decrease/reduce/relieve diarrhoea
- Decrease/reduce/relieve diarrhoea in healthy infants over 6 months of age
- Decrease/reduce/relieve diarrhoea in children over 12 years of age
- Decrease/reduce/relieve diarrhoea in children
- Helps reduce occurrence of diarrhoea in children over 12 years of age
- Helps reduce occurrence of diarrhoea in children
- Helps reduce occurrence of diarrhoea
- Helps reduce occurrence of symptoms of traveller's diarrhoea
- Maintain/support healthy bowel/colon function
- Maintain/support healthy bowel/colon function in children
- Maintain/support healthy bowel/colon function in healthy infants over 6 months of age
- Maintain/support healthy bowel/colon function in children over 12 years of age
- Maintain/support healthy digestive system function in healthy infants over 6 months of age
- Maintain/support healthy digestive system function in children over 12 years of age
- Maintain/support healthy digestive system function
- Maintain/support healthy digestive system function in children
- Maintain/support gastrointestinal system health in healthy infants over 6 months of age
- Maintain/support gastrointestinal system health in children
- Maintain/support gastrointestinal system health in children over 12 years of age
- Maintain/support gastrointestinal system health
- Decrease/reduce/relieve gastrointestinal pain in children

Indication Requirements



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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 not imply or refer to gastro oesophageal reflux disease.

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

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).

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 Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

| | |
|--------------------------------------|---------------------|
| Lactobacillus rhamnosus | 5 billion organisms |
| Saccharomyces cerevisiae (Boulardii) | 5 billion organisms |

Other Ingredients (Excipients)

- calcium hydrogen phosphate dihydrate
- colloidal anhydrous silica
- disodium edetate
- gellan gum
- hypromellose
- magnesium stearate
- maltodextrin
- microcrystalline cellulose
- potable water
- potassium acetate
- sodium ascorbate
- sorbitan monostearate
- sucrose

Public Summary

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