



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

| | | |
|--------------------------------|---|-----------------------|
| Summary for ARTG Entry: | 313480 | Gut Relief with Honey |
| ARTG entry for | Medicine Listed | |
| Sponsor | Nutrition Care Pharmaceuticals Pty Ltd | |
| Postal Address | 25-31 Keysborough Avenue, Keysborough, VIC, 3173 Australia | |
| ARTG Start Date | 22/01/2019 | |
| 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 . Gut Relief with Honey

| Product Type | Effective Date |
|-------------------------|----------------|
| Single Medicine Product | 20/08/2019 |

Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support energy production
- Maintain/support eye health
- Helps maintain/support healthy acid/alkali balance in the body
- Maintain/support general health and wellbeing
- Maintain/support blood capillary health
- Maintain/support healthy mucous linings of the digestive system
- Maintain/support gastrointestinal system health
- Maintain/support healthy gastrointestinal function
- Maintain/support gastrointestinal mucosal membrane health
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support healthy gastrointestinal immune function
- Maintain/support muscle health
- Aid/assist/helps protein synthesis in the body
- Support healthy body stress recovery

Indication Requirements

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.



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

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

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 medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

Not suitable for infants under the age of twelve months (or words to that effect).

Additional Product information

Container information

| Type | Material | Life Time | Temperature | Closure | Conditions |
|---------------------|--------------|--------------|--------------|--------------|--------------|
| Multiple containers | Not recorded | Not recorded | Not recorded | Not recorded | Not recorded |

Pack Size/Poison information

| Pack Size | Poison Schedule |
|-----------|-----------------|
| | |

Components

1 . Formulation 1

Dosage Form Powder

Route of Administration Oral

Visual Identification

Active Ingredients

| | |
|---|------------------------|
| Aloe vera leaf Juice powder | 1 mg/g |
| Equivalent: Aloe vera (Fresh) | 200 mg/g |
| curcumin | 1.2755 mg/g |
| dibasic sodium phosphate | 20 mg/g |
| glutamine | 400 mg/g |
| Guar Gum | 20 mg/g |
| Honey | 150.5 mg/g |
| pectin | 20 mg/g |
| Peppermint Oil | 600 microgram/g |
| quercetin | 40 mg/g |
| Ulmus rubra stem bark inner Powder | 100 mg/g |

Other Ingredients (Excipients)

betadex
 colloidal anhydrous silica
 maltodextrin
 Stevia rebaudiana

Public Summary

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