



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	319287	Gut Relief with Honey Chewables
ARTG entry for	Medicine Listed	
Sponsor	Nutrition Care Pharmaceuticals Pty Ltd	
Postal Address	25-31 Keysborough Avenue, Keysborough, VIC, 3173 Australia	
ARTG Start Date	26/06/2019	
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 Chewables

Product Type	Effective Date
Single Medicine Product	26/06/2019

Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support energy production
- Helps maintain/support healthy acid/alkali balance in the body
- Maintain/support general health and wellbeing
- 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 muscle health

Indication Requirements

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



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

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

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, chewable

Route of Administration Oral

Visual Identification

Active Ingredients

Aloe vera leaf Juice powder	.167 mg
Equivalent: Aloe vera (Fresh)	33.4 mg
curcumin	.2478 mg
dibasic sodium phosphate	3.33 mg
glutamine	250 mg
Guar Gum	3.33 mg
Honey	12.5 mg
pectin	3.33 mg
quercetin	70 mg
Ulmus rubra stem bark inner Powder	16.7 mg

Other Ingredients (Excipients)

betadex
colloidal anhydrous silica
magnesium stearate
maltodextrin
menthol
microcrystalline cellulose
sorbitol
sucralose
xylitol

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