



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	355115	NUTRA-LIFE GUT RELIEF
ARTG entry for	Medicine Listed	
Sponsor	Vitaco Health Australia Pty Ltd	
Postal Address	PO Box 399, NORTH RYDE BC, NSW, 1670 Australia	
ARTG Start Date	17/02/2021	
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.

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 . NUTRA-LIFE GUT RELIEF

Product Type	Single Medicine Product	Effective Date	28/04/2021
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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 healthy eye function
- Maintain/support eye health
- Maintain/support healthy eyesight/vision
- Helps maintain/support healthy acid/alkali balance in the body
- Maintain/support general health and wellbeing
- Maintain/support hair health
- Maintain/support nail health/strength/thickness
- Demulcent/soothe irritated tissues
- Maintain/support bone health
- Maintain/support gastrointestinal system health
- Maintain/support healthy gastrointestinal function
- Maintain/support gastrointestinal mucosal membrane health
- Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal bloating/distention
- Decrease/reduce/relieve abdominal bloating/distention
- Soothe gastro-intestinal tract mucous membranes
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support healthy gastrointestinal immune function
- Maintain/support muscle health after exercise
- Aid/assist/helps protein synthesis in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Maintain/support cognitive function/mental function
- Maintain/support nerve conduction

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Maintain/support nervous system function
 Maintain/support skin health
 Maintain/support skin integrity/structure
 Maintain/support skin regeneration
 Maintain/support wound healing

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.

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

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

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

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

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

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

Product presentation must not imply or refer to gastro oesophageal reflux disease.

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Not recommended for use by pregnant and lactating women (or words to that effect).

If symptoms persist, seek the advice of a healthcare professional.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

Acacia	200 mg/g
Aloe vera leaf inner juice Powder	8.33 mg/g
Equivalent: Aloe vera (Dry)	1.67 g/g
Althaea officinalis root Extract dry concentrate	88.89 mg/g
Equivalent: Althaea officinalis (Dry)	266.67 mg/g
Curcuma longa rhizome Extract dry concentrate standardised	1.666 mg/g
Equivalent: Curcuma longa (Fresh)	274.89 mg/g
Cynara scolymus leaf Extract dry concentrate	16.67 mg/g
Equivalent: Cynara scolymus (Fresh)	833.33 mg/g
glutamine	333.33 mg/g
pectin	100 mg/g
quercetin dihydrate	33.33 mg/g
Ulmus rubra stem bark Powder	125 mg/g
zinc gluconate	9.69 mg/g

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Equivalent: zinc

1.25 mg/g

Other Ingredients (Excipients)

citric acid

colloidal anhydrous silica

Flavour

lecithin

malic acid

maltodextrin

microcrystalline cellulose

sodium bicarbonate

Steviol glycosides

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