



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	444372	Gut Calm + Restore
ARTG entry for	Medicine Listed	
Sponsor	The Trustee for Luxton Wellness Trust	
Postal Address	PO Box 6117, Hawthorn West, VIC, 3122 Australia	
ARTG Start Date	25/03/2024	
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 . Gut Calm + Restore

Product Type	Single Medicine Product	Effective Date	25/03/2024
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to demulcent/soothe irritated tissues
- Traditionally used in Western herbal medicine to demulcent/soothe irritated tissues
- Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
- Maintain/support intestinal health
- Aid/assist/helps digestion of (state nutrient)
- Maintain/support intestinal good/beneficial/friendly flora
- Nourish good/beneficial/friendly intestinal flora
- Maintain/support gastrointestinal system 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
- Traditionally used in Chinese medicine to decrease/reduce/relieve abdominal spasm
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
- Traditionally used in Western herbal medicine to soothe gastro-intestinal tract mucous membranes
- Traditionally used in Western herbal medicine to decrease/reduce/relieve digestive spasms
- Traditionally used in Western herbal medicine to digestive tonic/Improve digestive weakness
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support healthy gastrointestinal immune function
- Traditionally used in Western herbal medicine to relieve irritability
- Traditionally used in Western herbal medicine to calms the mind
- Traditionally used in Western herbal medicine to soothe/calm nerves
- Traditionally used in Western herbal medicine to calmative/nervous system relaxant



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Indication Requirements

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

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

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

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

The dose of fibre should be increased gradually. Fluid intake should be increased with an increasing dose of fibre.

Do not take powder alone. Mix with food or fluid.

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

Actinidia deliciosa fruit Powder	34.6875 mg/g
Aloe vera leaf inner Extract dry concentrate	141 microgram/g
Equivalent: Aloe vera (Dry)	28.2 mg/g
Althaea officinalis root Extract dry concentrate	18.75 mg/g
Equivalent: Althaea officinalis (Dry)	375 mg/g
bromelains	31.25 mg/g
Curcuma longa root Extract dry concentrate	32.895 mg/g
Equivalent: Curcuma longa (Dry)	986.85 mg/g
glutamine	125 mg/g
Glycyrrhiza glabra root Extract dry concentrate	47.5 mg/g
Equivalent: Glycyrrhiza glabra (Dry)	190 mg/g
guar galactomannan	312.5 mg/g
Matricaria chamomilla flower Extract dry concentrate	31.25 mg/g
Equivalent: Matricaria chamomilla (Dry)	250 mg/g
Saccharomyces cerevisiae (Boulardii)	12.5 mg/g
Zingiber officinale rhizome Extract dry concentrate	7.81 mg/g
Equivalent: Zingiber officinale (Dry)	156.25 mg/g

Other Ingredients (Excipients)

citric acid

colloidal anhydrous silica

Flavour

glycine

maltodextrin

microcrystalline cellulose

silicon dioxide

Stevia rebaudiana

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