



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	476353	Gut Repair Support
ARTG entry for	Medicine Listed	
Sponsor	Whole Health Studio	
Postal Address	4 Glenelg Avenue, Mermaid Beach, QLD, 4218 Australia	
ARTG Start Date	22/01/2025	
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 Repair Support

Product Type	Single Medicine Product	Effective Date	22/01/2025
---------------------	-------------------------	-----------------------	------------

Permitted Indications

- Helps enhance/promote healthy digestive system function
- Enhance/promote healthy digestion
- Maintain/support healthy digestion
- Maintain/support healthy mucous linings of the digestive system
- Traditionally used in Western herbal medicine to maintain/support healthy mucous linings of the digestive system
- Maintain/support digestive system health
- Helps restore good/beneficial/friendly intestinal/gut/bowel flora
- Helps enhance/improve/promote/increase healthy digestive system flora/good bacteria growth
- Helps enhance/improve/promote/increase intestinal good/beneficial/friendly bacteria growth
- Maintain/support gastrointestinal system health
- Traditionally used in Western herbal medicine to maintain/support gastrointestinal system health
- Helps enhance/promote gastrointestinal system health
- Traditionally used in Western herbal medicine to maintain/support gastrointestinal mucosal membrane health
- Traditionally used in Western herbal medicine to aids/assists repair of gastrointestinal/gut wall lining
- Helps decrease/reduce/relieve mild gastrointestinal tract inflammation
- Traditionally used in Western herbal medicine to helps decrease/reduce/relieve mild gastrointestinal tract inflammation
- Traditionally used in Western herbal medicine to soothe gastro-intestinal tract mucous membranes
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Relieve symptoms of acne
- Relieve minor skin eruptions
- Decrease/reduce/relieve symptoms of acne blackheads
- Helps reduce occurrence of blackheads
- Helps reduce occurrence of symptoms of acne
- Decrease/reduce/relieve pimples
- Helps reduce occurrence of pimples
- Maintain/support wound healing

Public Summary



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to serious immunological diseases.

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 use if pregnant or likely to become pregnant (or words to that effect)
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

Althaea officinalis root Extract dry concentrate	20 mg/g
Equivalent: Althaea officinalis (Dry)	400 mg/g
Bifidobacterium longum	.2 billion CFU/g
glutamine	400 mg/g
guar galactomannan	200 mg/g
polaprezinc	14.88 mg/g
Equivalent: zinc	3.2 mg/g
Ulmus rubra stem bark inner Extract dry concentrate	25 mg/g
Equivalent: Ulmus rubra (Dry)	100 mg/g

Other Ingredients (Excipients)

- citric acid
- colloidal anhydrous silica
- Flavour
- glycine
- Stevia rebaudiana

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.