



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	476010	Gut Cleanse Support
ARTG entry for	Medicine Listed	
Sponsor	Whole Health Studio	
Postal Address	4 Glenelg Avenue, Mermaid Beach, QLD, 4218 Australia	
ARTG Start Date	17/01/2025	
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 Cleanse Support

Product Type	Single Medicine Product	Effective Date	17/01/2025
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Permitted Indications

Traditionally used in Western herbal medicine to vermifuge/helps remove intestinal threadworms/pinworms

Traditionally used in Chinese medicine to vermifuge/helps remove intestinal threadworms/pinworms

Helps enhance/promote healthy digestive system function

Enhance/promote healthy digestion

Maintain/support healthy digestion

Maintain/support digestive system health

Maintain/support gastrointestinal system health

Helps enhance/promote gastrointestinal system health

Maintain/support immune system health

Maintain/support healthy immune system function

Indication Requirements

Product presentation must not imply or refer to other worms e.g. roundworm, tapeworm, hookworm.

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

Do not use if pregnant or likely to become pregnant (or words to that effect)

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Artemisia annua herb Extract dry concentrate	75 mg
Equivalent: Artemisia annua (Dry)	750 mg
Berberis vulgaris stem bark Extract dry concentrate	80 mg
Equivalent: Berberis vulgaris (Dry)	800 mg
Handroanthus impetiginosus stem bark inner Extract dry concentrate	50 mg
Equivalent: Handroanthus impetiginosus (Dry)	500 mg
Juglans nigra fruit hull Extract dry concentrate	75 mg
Equivalent: Juglans nigra (Dry)	375 mg
Silybum marianum fruit Extract dry concentrate	21.43 mg
Equivalent: Silybum marianum (Dry)	1.5 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
hypromellose
magnesium stearate
maltodextrin
microcrystalline cellulose
purified water

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