



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	308927	Gut Care
ARTG entry for	Medicine Listed	
Sponsor	Herbs of Gold Pty Ltd	
Postal Address	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
ARTG Start Date	3/09/2018	
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 Care

Product Type	Single Medicine Product	Effective Date	10/02/2022
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Permitted Indications

- Anti-inflammatory/relieve inflammation
- Traditionally used in Western herbal medicine to anti-inflammatory/relieve inflammation
- Demulcent/soothe irritated tissues
- Traditionally used in Western herbal medicine to demulcent/soothe irritated tissues
- Maintain/support intestinal health
- Maintain/support healthy digestive system function
- Maintain/support healthy digestive system function
- Maintain/support healthy digestion
- Maintain/support healthy mucous linings of the digestive system
- Maintain/support digestive system health
- Maintain/support intestinal good/beneficial/friendly flora
- Maintain/support gastrointestinal system health
- Maintain/support healthy gastrointestinal function
- Maintain/support gastrointestinal mucosal membrane health
- 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
- Soothe gastro-intestinal tract mucous membranes
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support healthy gastrointestinal immune function
- Traditionally used in Western herbal medicine to vulnerary/wound healing

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



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No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

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

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

Aloe vera leaf inner Juice powder	7.5 mg/g
Equivalent: Aloe vera (Fresh)	1.5 g/g
Calendula officinalis flower Extract dry concentrate	40 mg/g
Equivalent: Calendula officinalis (Dry)	400 mg/g
glutamine	700 mg/g
Glycyrrhiza glabra root Extract dry concentrate	30 mg/g
Equivalent: Glycyrrhiza glabra (Dry)	300 mg/g
quercetin dihydrate	20 mg/g
Saccharomyces cerevisiae (Boulardii)	25.0004 mg/g
Ulmus rubra stem bark inner Powder	40 mg/g
zinc amino acid chelate	15 mg/g
Equivalent: zinc	3 mg/g

Other Ingredients (Excipients)

colloidal anhydrous silica

Flavour

maltodextrin

sorbitan monostearate

Stevia rebaudiana

Public Summary

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