



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 373372 METAGENICS GASTRO AID

ARTG entry for Medicine Listed
Sponsor Metagenics (Aust) Pty Ltd
Postal Address PO Box 675, VIRGINIA BC, QLD, 4014
Australia
ARTG Start Date 24/08/2021
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 . METAGENICS GASTRO AID

Product Type Single Medicine Product **Effective Date** 24/08/2021

Permitted Indications

Demulcent/soothe irritated tissues
Decrease/reduce/relieve loss of appetite
Maintain/support healthy digestive system function
Maintain/support healthy digestion
Decrease/reduce/relieve abdominal bloating/distention
Decrease/reduce/relieve abdominal feeling of fullness
Decrease/reduce/relieve abdominal pain/discomfort
Relieve excessive belching
Decrease/reduce/relieve symptoms of indigestion/dyspepsia
Relieve digestive discomfort
Decrease/reduce/relieve symptoms of heartburn
Soothe gastro-intestinal tract mucous membranes
Maintain/support bile production
Decrease/reduce/relieve symptoms of stomach upsets

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to gastro oesophageal reflux disease.
Product presentation must not imply or refer to eating disorders.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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

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Additional Product information	
Pack Size/Poison information	
Pack Size	Poison Schedule
Components	
1 . Formulation 1	
Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	
Active Ingredients	
Curcuma longa rhizome Extract dry concentrate	100 mg
Equivalent: Curcuma longa (Dry)	2.5 g
Cynara scolymus leaf Extract dry concentrate	80 mg
Equivalent: Cynara scolymus (Dry)	2 g
Glycyrrhiza glabra root Extract dry concentrate standardised	75 mg
Equivalent: Glycyrrhiza glabra (Dry)	2062.5 mg
Matricaria chamomilla flower Extract dry concentrate	83.33 mg
Equivalent: Matricaria chamomilla (Dry)	500 mg
Other Ingredients (Excipients)	
calcium hydrogen phosphate dihydrate	
colloidal anhydrous silica	
disodium edetate	
gellan gum	
hypromellose	
magnesium stearate	
potable water	
potassium acetate	
silicon dioxide	

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