Public Summary

Summary for ARTG Entry:	210907 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	14/06/2013
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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**	30/04/2020

Permitted Indications

Traditionally used in Western herbal medicine to demulcent/soothe irritated tissues

Demulcent/soothe irritated tissues

Decrease/reduce/relieve loss of appetite

Maintain/support healthy digestive system function

Maintain/support healthy digestion

Traditionally used in Western herbal medicine to maintain/support healthy gastrointestinal function

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

Traditionally used in Western herbal medicine to soothe gastro-intestinal tract mucous membranes

Maintain/support bile production

Traditionally used in Western herbal medicine to maintain/support stomach function

Decrease/reduce/relieve symptoms of stomach upsets

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 eating disorders.

Product presentation must not imply or refer to disease in any body organ.

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)

Do not use while breastfeeding.

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

Use in children under 12 years is not recommended.

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 root and 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
Foeniculum vulgare seed Extract dry concentrate	**166.67 mg**
Equivalent: Foeniculum vulgare (Dry)	1.67 g
Glycyrrhiza glabra	**75 mg**
Matricaria chamomilla flower Extract dry concentrate	**83.33 mg**
Equivalent: Matricaria chamomilla (Dry)	500 mg

Other Ingredients (Excipients)

colloidal anhydrous silica
disodium edetate
gellan gum
hypromellose
magnesium stearate
microcrystalline cellulose
potable water
potassium acetate
silicon dioxide

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