



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	350974	Intestamine
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
ARTG Start Date	7/12/2020	
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 . Intestamine

Product Type	Single Medicine Product	Effective Date	7/12/2020
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Permitted Indications

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

Decrease/reduce/relieve symptoms of indigestion/dyspepsia

Traditionally used in Western herbal medicine to helps decrease/reduce/relieve symptoms of mild gastritis

Decrease/reduce/relieve symptoms of heartburn

Traditionally used in Western herbal medicine to helps decrease/reduce/relieve mild gastrointestinal tract inflammation

Decrease/reduce/relieve gastrointestinal pain

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.

Label statement: If symptoms persist or worsen talk to your medical practitioner.

Product presentation must only refer to mild gastritis.

Product presentation must not imply or refer to gastro oesophageal reflux disease.

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).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

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Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

Aloe vera leaf inner Juice dry	500 microgram/g
Equivalent: Aloe vera (Juice fresh)	100 mg/g
Citrus bioflavonoids extract	40 mg/g
curcumin	3 mg/g
glutamine	400 mg/g
Mastic	109.9967 mg/g
pectin	20 mg/g
Ulmus rubra stem bark inner Powder	100 mg/g

Other Ingredients (Excipients)

citric acid
colloidal anhydrous silica
Flavour
Ghatti Gum
magnesium stearate
maltodextrin
maltose
microcrystalline cellulose
Steviol glycosides

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