



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	319072	PepZin Pro
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	19/06/2019	
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 . PepZin Pro

Product Type	Single Medicine Product	Effective Date	25/01/2022
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Decrease/reduce/relieve diarrhoea
Relief of symptoms of medically diagnosed Irritable Bowel Syndrome
Maintain/support healthy digestive system function
Maintain/support digestive system health
Maintain/support intestinal good/beneficial/friendly flora
Helps maintain/support good/beneficial/friendly gut flora during antibiotic use
Help restore good/beneficial/friendly gut flora after antibiotic use
Decrease/reduce/relieve abdominal bloating/distention
Decrease/reduce/relieve abdominal pain/discomfort
Helps decrease/reduce/relieve symptoms of mild gastritis
Linked indication - Decrease/reduce/relieve abdominal bloating/distention
Linked indication - Decrease/reduce/relieve gastrointestinal pain
Linked indication - Decrease/reduce/relieve nausea
Decrease/reduce/relieve symptoms of heartburn
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support 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.

Product presentation must only refer to medically diagnosed IBS.

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

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

Label statement: Seek medical advice if diarrhoea persists for more than: 6 hours in infants under 6 months, 12 hours in children under 3 years, 24 hours in children aged 3 to 6 years or 48 hours in adults and children over 6 years (or words to that effect).

Product presentation must only refer to mild gastritis.



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Standard Indications

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).

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

Lactobacillus helveticus	200 million CFU
Lactobacillus rhamnosus	3.8 billion CFU
polaprezinc	25 mg
Equivalent: zinc	5.56 mg

Other Ingredients (Excipients)

ascorbic acid
colloidal anhydrous silica
hypromellose
magnesium stearate
microcrystalline cellulose
potable water
potato starch

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