



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	319072	PepZin Pro
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	FIT-BioCeuticals Limited	
<b>Postal Address</b>	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
<b>ARTG Start Date</b>	19/06/2019	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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 nausea  
    Linked indication - Decrease/reduce/relieve gastrointestinal pain  
    Linked indication - Decrease/reduce/relieve abdominal bloating/distention  
Decrease/reduce/relieve symptoms of heartburn  
Maintain/support immune system health  
Maintain/support healthy immune system function  
Maintain/support wound healing

### Indication Requirements

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

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

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.

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

Product presentation must not imply or refer to serious immunological diseases.

Product presentation must only refer to medically diagnosed IBS.



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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**

<b>Lactobacillus helveticus</b>	<b>200 million CFU</b>
<b>Lactobacillus rhamnosus</b>	<b>3.8 billion CFU</b>
<b>polaprezinc</b>	<b>25 mg</b>
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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