



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	404523	Enterozyme
ARTG entry for	Medicine Listed	
Sponsor	Bio-Practica Pty Ltd	
Postal Address	651 Portrush Road, GLEN OSMOND, SA, 5064 Australia	
ARTG Start Date	8/02/2023	
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 . Enterozyme

Product Type	Single Medicine Product	Effective Date	24/02/2023
---------------------	-------------------------	-----------------------	------------

Permitted Indications

Traditionally used in Ayurvedic medicine to vipachini/aids digestion
Traditionally used in Chinese medicine to warm and nourish/strengthen stomach
Traditionally used in Western herbal medicine to orexigenic/improve/promote healthy appetite
Traditionally used in Ayurvedic medicine to decrease/reduce/relieve loss of appetite
Traditionally used in Western herbal medicine to decrease/reduce/relieve loss of appetite
Traditionally used in Western herbal medicine to maintain/support healthy appetite
Traditionally used in Western herbal medicine to decrease/reduce/relieve colic (wind/gas pain)
Traditionally used in Ayurvedic medicine to decrease/reduce/relieve flatulence/carminative
Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
Traditionally used in Western herbal medicine to maintain/support healthy digestion
Aid/assist/helps digestion of (state nutrient)
Traditionally used in Western herbal medicine to sialagogue/promote saliva production
Traditionally used in Western herbal medicine to bitter tonic/stimulate gastric secretions
Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal bloating/distention
Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal feeling of fullness
Traditionally used in Ayurvedic medicine to decrease/reduce/relieve abdominal pain/discomfort
Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal spasm
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
Traditionally used in Western herbal medicine to relieve digestive discomfort
Traditionally used in Western herbal medicine to digestive tonic/Improve digestive weakness
Traditionally used in Western herbal medicine to decrease/reduce/relieve nausea

Indication Requirements

Product presentation must not imply or refer to eating disorders.

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

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

If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

you.

If Ayurvedic terminology is used on medicine label, label statement: Talk to a Ayurvedic practitioner/health professional if you are unsure if this medicine is right for you.

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

No Warnings included on Record

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

bromelains	250 mg
Gentiana lutea root and rhizome Extract dry concentrate	250 mg
Equivalent: Gentiana lutea (Dry)	1 g
Zingiber officinale rhizome Extract dry concentrate	100 mg
Equivalent: Zingiber officinale (Dry)	1 g

Other Ingredients (Excipients)

colloidal anhydrous silica
hypromellose
magnesium stearate
maltodextrin
potable water

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary