



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	328366	Digestive Zyme
ARTG entry for	Medicine Listed	
Sponsor	Interclinical Laboratories Pty Ltd	
Postal Address	PO Box 6474, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	8/01/2020	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

Conditions

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 . Digestive Zyme

Product Type	Single Medicine Product	Effective Date	8/01/2020
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Permitted Indications

Traditionally used in Western herbal medicine to decrease/reduce/relieve loss of appetite
Traditionally used in Western herbal medicine to aperient/laxative
Traditionally used in Western herbal medicine to decrease/reduce/relieve colic (wind/gas pain)
Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
Maintain/support healthy digestive system function
Maintain/support healthy digestion
Aid/assist/helps digestion of fats/fatty acids/triglycerides/lipid
Aid/assist digestion of lactose
Aid/assist/helps digestion of (state nutrient)
Traditionally used in Western herbal medicine to bitter tonic/stimulate gastric secretions
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

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to gastro oesophageal reflux disease.
Label statement for stimulant laxatives: Prolonged use may cause serious bowel problems.
Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.
Product presentation must not imply or refer to eating disorders.
Label statement: Drink plenty of water (or words to that effect).
Label statement: Do not use when abdominal pain, nausea or vomiting are present or if you develop diarrhoea. If you are pregnant or breastfeeding - seek the advice of a healthcare professional before taking this product (or words to that effect).
Product presentation must not refer to or imply weight loss.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings



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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

Berberis vulgaris stem bark Extract dry concentrate	83.33 mg
Equivalent: Berberis vulgaris (Dry)	500 mg
Cynara scolymus leaf Extract dry concentrate	5 mg
Equivalent: Cynara scolymus (Fresh)	250 mg
glycine	10 mg
lipase	63 LipU
protease	11.5 Thousand HUT
taurine	10 mg
tilactase	2 thousand ALU
Zingiber officinale rhizome Extract dry concentrate	50 mg
Equivalent: Zingiber officinale (Dry)	250 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

dextrin

hypromellose

magnesium stearate

maltodextrin

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