



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	279633	Digest-Zymes
ARTG entry for	Medicine Listed	
Sponsor	Herbs of Gold Pty Ltd	
Postal Address	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
ARTG Start Date	26/08/2016	
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 . Digest-Zymes

Product Type	Single Medicine Product	Effective Date	18/10/2021
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Permitted Indications

Traditionally used in Western herbal medicine to maintain/support healthy appetite
Maintain/support healthy digestive system function
Traditionally used in Western herbal medicine to maintain/support healthy digestive system function
Maintain/support healthy digestion
Aid/assist/helps digestion of fats/fatty acids/triglycerides/lipid
Aid/assist digestion of glucose/sugar/carbohydrates
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 symptoms of indigestion/dyspepsia
Linked indication - Decrease/reduce/relieve abdominal pain/discomfort
Linked indication - Decrease/reduce/relieve abdominal feeling of fullness
Linked indication - Decrease/reduce/relieve abdominal bloating/distention
Traditionally used in Western herbal medicine to digestive tonic/Improve digestive weakness
Traditionally used in Western herbal medicine to cholagogue/promote bile flow from gall bladder

Indication Requirements

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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

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

Product presentation must not imply or refer to eating disorders.

Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.

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



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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

Amylase	10 thousand DU
bromelains	1.5 million PU
cellulase	125 CU
Gentiana lutea root Extract dry concentrate	120 mg
Equivalent: Gentiana lutea (Dry)	600 mg
lipase	400 LipU
protease	60 Thousand HUT
tilactase	1.5 thousand ALU

Other Ingredients (Excipients)

hypromellose

medium chain triglycerides

microcrystalline cellulose

purified water

tapioca starch

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