Professional Information for GI-ZYME®

COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT
This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS
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1. NAME OF THE MEDICINE
GI-ZYME® capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each vegetable capsule contains:

Acacia senegal (L.) Willd. (Acacia)	90 mg
Beta vulgaris L. (Beet) [root 23,5:1 extract, providing 940 mg dried herb equivalent]	40 mg
Foeniculum vulgare Mill. (Fennel) [seed]	24 mg
Zingiber officinale Roscoe (Ginger) [rhizome]	24 mg
Mentha × piperita L. (Peppermint) [leaf]	24 mg
Astragalus gummifer Labill. (Tragacanth)	9 mg
Aloe vera (L.) Burm.f. (Aloe) [inner leaf juice]	0,046 mg
Manapol® *Aloe vera* (L.) Burm.f. (Aloe) [inner leaf gel, 415:1 extract, providing 19 mg fresh herb equivalent]	0,046 mg
Bromelain	100 mg
Amylase	33 mg (4 950 FCC DU)
Alpha-galactosidase	30 mg
Protease 4.5	30 mg
Lipase	25 mg (1 250 FCC LU)
Protease 3.0	23,36 mg
Protease 6.0	16 mg
Lactase	10 mg (1 000 FCC ALU)
Cellulase	2,5 mg (200 FCC CU)
Calcium pantothenate	2,48 mg
providing pantothenic acid	2,24 mg
Invertase	1 mg (32,79 FCC INVU)

MANNATECH®

Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Hard capsules.
Greyish, pink powder in a clear capsule.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

GI-ZYME® is a combination complementary medicine that is formulated to maintain healthy digestive function. The enzymatic blend improves digestion by breaking down proteins, fats and carbohydrates.

4.2 Posology and method of administration

Adults:
Take one capsule with each meal.

A health care provider should be consulted for prolonged use (for use beyond 4 weeks).

Do not exceed the recommended dosage.

Paediatric population:
GI-ZYME® is not suitable for children under 18 years of age.

4.3 Contraindications

- Hypersensitivity to any of the ingredients listed in section 2 or to any of the excipients listed in section 6.1.
- Abnormal constrictions of the gastrointestinal tract, potential or existing intestinal blockage, atonic bowel, appendicitis, inflammatory colon disease (e.g. Crohn's disease or ulcerative colitis), abdominal pain of unknown origin, undiagnosed rectal bleeding, severe dehydration with depleted water or electrolytes, haemorrhoids or diarrhoea.
- Pregnancy or lactation

4.4 Special warnings and precautions for use

Surgery:
GI-ZYME® might interfere with blood glucose control and increase the risk of bleeding during and after surgical procedures. Patients should be advised to discontinue GI-ZYME® at least 2 weeks prior to any surgical procedures (see section 4.5).

Pineapple allergy:
Patients allergic to pineapple might have an allergic reaction to GI-ZYME®. In such cases, patients should be advised to discontinue GI-ZYME®.

Patients with gallstones, anaemia or a kidney disorder should consult a health care provider prior to use.

Patients with faecal impaction or symptoms such as abdominal pain, nausea, vomiting or fever should consult a health care provider prior to use (see section 4.3).

Patients should consult a health care provider if they have gastrointestinal lesions/ulcers or want to use GI-ZYME® for a prolonged period (use beyond 4 weeks).

If abdominal pain, cramps, spasms and/or diarrhoea is experienced after taking GI-ZYME®, patients should stop taking GI-ZYME® or reduce the dose.

Patients should consult a health care provider if their symptoms persist or worsen.

4.5 Interaction with other medicines and other forms of interaction

Anticoagulant or antiplatelet medicines:
GI-ZYME® may potentiate the effects of anticoagulant and antiplatelet medicines or herbal supplements with blood thinning effects (see section 4.4).

Antidiabetic medicines:
Concomitant use of GI-ZYME® with antidiabetic medicines or herbal supplements with blood sugar-lowering effects may interfere with blood glucose control and caution is advised during concomitant use (see section 4.4).

Patients taking anti-inflammatory medicines, antibiotics or cardiac medicines (e.g. cardiac glycosides or antidysrhythmic medicines) should consult a health care provider prior to use.

Patients taking thiazide diuretics, corticosteroids, liquorice root, or other medicines or health products that may aggravate electrolyte imbalance, should consult with a health care provider prior to use.

4.6 Fertility, pregnancy and lactation

GI-ZYME® should not be used during pregnancy and lactation (see section 4.3).

4.7 Effects on ability to drive and use machines

GI-ZYME® is unlikely to affect the ability to drive and use machines.

4.8 Undesirable effects

Immune system disorders:
Less frequent: hypersensitivity/allergic reactions.

Gastrointestinal disorders:
Frequent: abdominal/gastrointestinal discomfort, heartburn, diarrhoea, burping, gastric upset

Less frequent: abdominal pain and cramps, abdominal bloating, nausea, vomiting, flatulence.

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of GI-ZYME® is important. It allows continued monitoring of the benefit/risk balance of GI-ZYME®. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the Adverse Drug Reaction Reporting Form, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity. See section 4.8.

In the event of overdose, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

Category and class: D33.7 Combination product.

Mechanism of action:
Acacia gum is an indigestible, water-soluble dietary fiber.

Alpha-galoctosidase is a digestive enzyme that helps prevent gastrointestinal intolerance of oligosaccharides/fermentable carbohydrates.

It helps to reduce gas production/flatulence following a meal rich in oligosaccharides/fermentable carbohydrates (such as vegetables, pulses/legumes/beans and whole grains).

Aloe has anti-inflammatory and detoxification properties.

Beet has anti-inflammatory properties.

Bromelain is a digestive enzyme obtained from the fruit and stem of a pineapple, with anti-inflammatory properties.

Cellulase is an enzyme commonly used together with other digestive enzymes for digestive disorders.

Fennel increases gastric acid secretion and the activity of digestive enzymes.

Ginger helps to relieve digestive upset including lack of appetite, nausea, digestive spasms, indigestion, dyspepsia, and flatulent colic (carminative).

Invertase is an enzyme that breaks down sucrose to glucose and fructose.

Lactase is a digestive enzyme that helps with the digestion of foods containing lactose.

Lipase is a digestive enzyme that aids in fat digestion.

Pantothenic acid helps to metabolise carbohydrates, fats and proteins.

Peppermint aids in digestion and helps to relieve an upset stomach.

Protease is a digestive enzyme that helps with the digestion of proteins.

When ingested, the bulk of tragacanth stretches the intestinal wall, increasing peristalsis. It increases stool mass and decreases gastrointestinal (GI) transit time.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium phosphate dibasic (E341 (ii))
Capsule (containing hypromellose).
Silicon dioxide
Stearic acid.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C, in a dry place.

Keep in the original container until required for use.

Do not use if blister strip is torn or broken.

6.5 Nature and contents of container

Aluminium blisters strips containing 10 capsules per blister strip, packed in an outer carton.

Pack size 60 capsules.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

LeBasi Pharmaceuticals (Pty) Ltd
San Domenico Building, Ground Floor, Unit 6
10 Church Street, Durbanville 7551, South Africa

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

September 2021.