MANNATECH®

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PATIENT INFORMATION LEAFLET
GI-ZYME®

SCHEDULING STATUS
S0

GI-ZYME® capsules
Multiple substance formulation.
Sugar free.

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

Read all of this leaflet carefully because it contains important information for you
GI-ZYME® is available without a doctor's prescription. Nevertheless, you still need to take GI-ZYME® carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share GI-ZYME® with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 4 weeks.

What is in this leaflet

1. What GI-ZYME® is and what it is used for.
2. What you need to know before you take GI-ZYME®.
3. How to take GI-ZYME®.
4. Possible side effects.
5. How to store GI-ZYME®.
6. Contents of the pack and other information.

1. What GI-ZYME® is and what it is used for
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.

2. What you need to know before you take GI-ZYME®
Do not take GI-ZYME®:
- If you are hypersensitive (allergic) to any of the active ingredients or any of the other ingredients of GI-ZYME® (see section 6).
- If you have abnormal constrictions of your digestive tract, or a lazy or blocked large colon (causing chronic constipation).

- If you have appendicitis (inflammation of your appendix).
- If you have an inflammatory colon disease (e.g. Crohn's disease or ulcerative colitis).
- If you have abdominal pain with an unknown cause.
- If you have undiagnosed rectal bleeding.
- If you are severely dehydrated.
- If you have haemorrhoids (piles) or diarrhoea.
- If you are pregnant or breastfeeding.

Warnings and precautions
Take special care with GI-ZYME®
- If you have a bleeding disorder.
- If you are diabetic and you are taking medicines to control your blood sugar levels.
- If you are having any surgical procedure done. You should stop taking GI-ZYME® two weeks before an operation.
- If you are allergic to pineapple.
- If you experience abdominal pain, cramps, spasms and/or diarrhoea after taking GI-ZYME®, you should stop taking GI-ZYME® or reduce your dose of GI-ZYME®.

You should consult a health care provider before taking GI-ZYME®:
- If you have gallstones or anaemia (causing fatigue, loss of energy and pale skin).
- If you have symptoms such as nausea, vomiting or fever.
- If you have kidney problems.
- If you have stomach ulcers or want to use GI-ZYME® for a prolonged period of time (longer than 4 weeks).

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

Other medicines and GI-ZYME®
Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)
Tell your doctor or pharmacist if you are currently using:
- anticoagulant medicines (used to prevent your blood from clotting) or herbal supplements with blood thinning effects;
- antidiabetic medicine (used to treat high blood sugar);
- cardiac medicines (e.g. cardiac glycosides [used to treat heart failure], antidysrhythmic medicines [used to prevent and treat abnormal heartbeats]), anti-inflammatory medicines and antibiotics (used to treat bacterial infections);
- diuretics (water pills), corticosteroids (used to treat inflamed areas of your body), liquorice root or other medicines or products that may worsen electrolyte imbalance.

GI-ZYME® with food
See section 3.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking GI-ZYME®.

Do not use GI-ZYME® if you are pregnant or breastfeeding (see **Do not take GI-ZYME®**).

Driving and using machines
GI-ZYME® is unlikely to have an effect on your ability to drive a vehicle and use machines.

3. How to take GI-ZYME®
Always take GI-ZYME® exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults: Take one capsule with each meal.
You should consult a health care provider for prolonged use (for use beyond 4 weeks).
Do not exceed the recommended dose.

If you have the impression that the effect of GI-ZYME® is too strong or too weak, tell your doctor or pharmacist.

If you take more GI-ZYME® than you should
In the event of an overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre. Take this leaflet and the remaining capsules with you so the doctor will know what you have taken.

If you forget to take GI-ZYME®
Take your next dose at your regular time.
Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects
GI-ZYME® can have side effects.
Not all side effects reported for GI-ZYME® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking GI-ZYME®, please consult your health care provider for advice.

If any of the following happens, stop taking GI-ZYME® and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to GI-ZYME®. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:
Side effects occurring frequently:
- stomach problems, heartburn, diarrhoea, burping.

Side effects occurring less frequently
- stomach pain, cramps or bloating, nausea (feeling sick), vomiting (being sick), flatulence (wind).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.
By reporting side effects, you can help provide more information on the safety of GI-ZYME®.

5. How to store GI-ZYME®
- Store at or below 25 °C, in a dry place.
- Keep in the original container until required for use.
- Do not use if the blister strip is torn or broken.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the packaging.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information
What GI-ZYME® contains
Each vegetable capsule contains:

Acacia senegal (L.) Willd. (Acacia)	90,046 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
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 (15 000 FCC HUT)

Lipase	25 mg (1 250 FCC LU)
Protease 3.0	23,36 mg (350,4 FCC SAP)
Protease 6.0	16 mg (6 400 FCC HUT)
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)

The other ingredients are calcium phosphate dibasic (E341 [ii]), the capsule (containing hypromellose), silicon dioxide and stearic acid.

What GI-ZYME® looks like and contents of the pack
Greyish, pink powder in a clear capsule.
Aluminium blister strips containing 10 capsules per blister strip, packed in an outer carton.
Pack size 60 capsules.

Holder of Certificate of Registration
LeBasi Pharmaceuticals (Pty) Ltd
San Domenico Building, Unit 6, Ground Floor
10 Church Street
Durbanville 7551
Suid-Afrika
Tel.: 087 551 3245

This leaflet was last revised in
September 2026

Registration number
To be allocated.

Access to corresponding Professional Information
https://library.mannatech.com/download/12237

PASIËNTINLIGTINGSBLAD GI-ZYME®

SKEDULERINGSTATUS
S0

GI-ZYME® kapsules
Formule met verskeie bestanddele.
Suikervry.

KOMPLEMENTÊRE MEDISYNE: KOMBINASIEPRODUK
Hierdie ongeregistreerde medisyne is nie vir gehalte, veiligheid of beoogde gebruik deur SAHPRA geëvalueer nie

Lees hierdie hele inligtingsblad noulettend deur want dit bevat inligting wat belangrik is vir jou.
GI-ZYME® is beskikbaar sonder 'n dokter se voorskrif. Jy moet GI-ZYME® nietemin steeds versigtig neem om die beste resultate te verkry.
- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Moenie GI-ZYME® met 'n ander persoon deel nie.
- Vra gerus jou apteker indien jy verdere inligting of advies nodig het.
- Jy moet 'n dokter gaan spreek indien jou simptome vererger of nie verbeter binne 4 weke nie.

Wat is in hierdie inligtingsblad

1. Wat is GI-ZYME® en waarvoor word dit gebruik.
2. Wat jy moet weet voordat jy GI-ZYME® neem.
3. Hoe om GI-ZYME® te neem.
4. Moontlike newe-effekte.
5. Hoe om GI-ZYME® te bêre.
6. Inhoud van die pak en ander inligting.

1. Wat is GI-ZYME® en waarvoor word dit gebruik
GI-ZYME® is 'n kombinasieproduk komplementêre medisyne wat geformuleer is om 'n gesonde spysverteringstelsel te handhaaf. Die ensiematiese mengsel verbeter vertering deur proteïene, vette en koolhidrate af te breek.

2. Wat jy moet weet voordat jy GI-ZYME® neem
Moenie GI-ZYME® neem nie:
- Indien jy hipersensitief (allergies) is vir enige van die aktiewe bestanddele of vir enige van die ander bestanddele van GI-ZYME® (sien afdeling 6).
- Indien jy abnormale vernouings in jou spysverteringstelsel het, of 'n lui of geblokkeerde dikderm het (wat chroniese hardlywigheid veroorsaak).
- Indien jy appendisitis het (blindedermontsteking).

- Indien jy 'n inflammatoriese siekte van die kolon het (bv. Crohn se siekte of ulseratiewe kolitis).
- Indien jy buikpyn het waarvan die oorsaak onbekend is.
- Indien jy ongediagnoseerde rektale bloeding het.
- Indien jy erg gedehidreer (ontwater) is.
- Indien jy hemorroïede (aambeie) of diarree het.
- Indien jy swanger is of borsvoed.

Waarskuwings en voorsorgmaatreëls
Wees versigtig met GI-ZYME®:
- Indien jy 'n bloedingsteuring het.
- Indien jy diabeties is en jy medisyne neem om jou bloedsuikervlakke te beheer.
- Indien jy enige chirurgiese prosedure moet ondergaan. Jy moet twee weke voor 'n operasie ophou op GI-ZYME® te neem.
- Indien jy allergies vir pynappel is.
- Indien jy buikpyn, -krampe, -spasmas en/of diarree ondervind nadat jy GI-ZYME® geneem het, moet jy ophou om GI-ZYME® te neem of jou dosis daarvan verlaag.

Jy moet 'n gesondheidsorgverskaffer raadpleeg voordat jy GI-ZYME® neem:
- Indien jy galstene of anemie het (veroorsaak moegheid, gebrek aan energie en bleekheid).
- Indien jy simptome soos naarheid, braking of koors het.
- Indien jy nierprobleme het.
- Indien jy maagsere het, of jy wil GI-ZYME® langdurig gebruik.

Kinders:
GI-ZYME® is nie geskik vir kinders jonger as 18 jaar nie.

Ander medisyne en GI-ZYME®
Sê altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)
Sê vir jou dokter of apteker indien jy tans die volgende gebruik:

- antikoagulantmedisyne (gebruik om te keer dat klonte in jou bloed vorm) of kruie-aanvullings met bloedverdunnende effekte;
- antidiabetiese medisyne (gebruik om hoë bloedsuiker te behandel);
- hartmedisyne (bv. kardiale glikosiede [gebruik om hartversaking te behandel], antidisritmiese medisyne [gebruik om abnormale hartritmes te voorkom en behandel]), antiinflammatoriese medisyne en antibiotika (gebruik om bakteriële infeksies te behandel);
- diuretika (waterpille), kortikosteroïede (gebruik om inflammasie in jou liggaam te behandel), soethoutwortel of ander medisynes of produkte wat 'n elektrolietwanbalans kan vererger.

GI-ZYME® met kos
Sien afdeling 3.

Swangerskap en borsvoeding
Indien jy swanger is of jou baba borsvoed, vermoed dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy GI-ZYME® neem.
Moenie GI-ZYME® gebruik indien jy swanger is of borsvoed nie (sien **Moenie GI-ZYME® neem nie**).

Bestuur en die gebruik van masjiene
Dit is onwaarskynlik dat GI-ZYME® jou vermoë om 'n voertuig te bestuur en masjiene te gebruik sal affekteer.

3. Hoe om GI-ZYME® te neem

Neem GI-ZYME® altyd presies soos wat in hierdie inligtingsblad aangedui word, of soos wat jou dokter of apteker vir jou aangewys het. Vra gerus jou dokter of apteker indien jy onseker is.
Volwassenes: Neem een kapsule met elke maaltyd.
Moenie die aanbevole dosis oorskry nie.

Indien jy die indruk kry dat die uitwerking van GI-ZYME® te sterk of te swak is, bespreek dit met jou dokter of apteker.

Wat om te doen indien jy meer GI-ZYME® geneem het as wat jy moet
In die geval van 'n oordosis, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum. Neem hierdie inligtingsblad en die oorblywende kapsules saam sodat die dokter kan sien wat jy geneem het.

Indien jy vergeet het om GI-ZYME® te neem
Neem jou volgende dosis op die gewone tyd.
Moenie 'n dubbele dosis neem om te vergoed vir individuele dosisse wat vergeet is nie.

4. Moontlike newe-effekte

GI-ZYME® kan newe-effekte hê.
Nie alle newe-effekte wat vir GI-ZYME® gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of indien jy enige ongunstige effekte ondervind terwyl jy GI-ZYME® neem, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om GI-ZYME® te neem en sê dadelik vir jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- swelling van jou hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak met sluk en asemhaling
- uitslag of gejeuk
- floute.

Hierdie is baie ernstige newe-effekte. Indien jy enige daarvan ondervind, mag jy 'n ernstige allergiese reaksie op GI-ZYME® gehad het. Jy mag dringende mediese bystand of hospitalisasie benodig.

Sê vir jou dokter indien jy enige van die volgende opmerk:
Newe-effekte wat dikwels voorkom
- maagprobleme, sooibrand, diarree, bring winde op.

Newe-effekte wat minder dikwels voorkom
- maagpyn, krampe of opgeblasenheid, naarheid, braking, winderigheid.

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, lig asseblief jou dokter of apteker in.

Rapportering van newe-effekte
Indien jy newe-effekte ondervind, bespreek dit met jou dokter of apteker. Jy kan ook newe-effekte aan SAHPRA rapporteer via die Med Safety-toepassing (Medsafety X SAHPRA) en eReporting-platform (who-umc.org), wat op SAHPRA se webwerf beskikbaar is.
Deur newe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van GI-ZYME® te verskaf.

5. Hoe om GI-ZYME® te bêre
- Bêre by of onder 25 °C, op 'n droë plek.
- Hou in die oorspronklike verpakking tot nodig vir gebruik.
- Moenie gebruik indien die stulpstrook geskeur of beskadig is nie.
- BÊRE ALLE MEDISYNE BUITE BEREIK VAN KINDERS.
- Moenie gebruik ná die vervaldatum wat op die verpakking gedruk is nie.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moenie ongebruikte medisyne in dreine en rioolsisteme (bv. toilette) wegdoen nie.

6. Inhoud van die pak en ander inligting
Wat GI-ZYME® bevat
Elke plantaardige kapsule bevat:

Acacia senegal (L.) Willd. (Akasia)	90,046 mg
Beta vulgaris L. (Beet) [wortel, 23,5:1 ekstrak, lewer 940 mg gedroogde kruie ekwivalent]	40 mg
Foeniculum vulgare Mill. (Vinkel) [saad]	24 mg
Zingiber officinale Roscoe (Gemmer) [risoom]	24 mg
Mentha × piperita L. (Peperment) [blaar]	24 mg
Astragalus gummifer Labill. (Tragakant)	9 mg
Manapol® *Aloe vera* (L.) Burm.f. (Aalwyn) [droë jel van binneste blaar, 415:1 ekstrak, lewer	0,046 mg

19 mg vars kruie ekwivalent]	
Bromelien	100 mg
Amilase	33 mg (4 950 VCK DE)
Alfa-galaktosidase	30 mg
Protease 4.5	30 mg (15 000 VCK HET)
Lipase	25 mg (1 250 VCK LE)
Protease 3.0	23,36 mg (350,4 VCK SSP)
Protease 6.0	16 mg (6 400 VCK HET)
Laktase	10 mg (1 000 VCK SLE)
Sellulase	2,5 mg (200 VCK SE)
Kalsiumpantotenaat	2,48 mg
lewer pantoteensuur	2,24 mg
Invertase	1 mg (32,79 VCK INVE)

Die ander bestanddele is dibasiese kalsiumfosfaat (E341 [ii]), die kapsule (bevat hipromellose), silikondioksied en stearіensuur.

Hoe GI-ZYME® lyk en inhoud van die verpakking
Gryserige, pienk poeier in ’n deurskynende kapsule.
Aluminium stulpstroke wat 10 kapsules per stulpstrook bevat, verpak in ‘n buitenste karton.
Verpakkingsgrootte 60 kapsules.

Houer van die Registrasiesertifikaat
LeBasi Pharmaceuticals (Edms.) Bpk.
San Domenico-gebou, Eenheid 6, Grondvloer
Kerkstraat 10
Durbanville 7551
Suid-Afrika
Tel.: 087 551 3245

Hierdie inligtingsblad is laas hersien in
September 2026

Registrasienommer
Sal met registrasie deur SAHPRA toegeken word.

Toegang tot die ooreenstemmende Professionele Inligtingsblad
https://library.mannatech.com/download/12237

PROFESSIONAL INFORMATION FOR GI-ZYME®

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

SCHEDULING STATUS
S0

1. NAME OF THE MEDICINE
GI-ZYME® capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each vegetable capsule contains:

Acacia senegal (L.) Willd. (Acacia)	90,046 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
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 (15 000 FCC HUT)
Lipase	25 mg (1 250 FCC LU)
Protease 3.0	23,36 mg (350,4 FCC SAP)
Protease 6.0	16 mg (6 400 FCC HUT)
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)

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

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: D 33.7 Combination Product.

Mechanism of action:

Acacia gum is an indigestible, water-soluble dietary fiber.
Alpha-galactosidase 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 blister 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, Unit 6, Ground Floor
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 2026