Professional Information for GI-PROBALANCE®

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-PROBALANCE® sachets each containing 8,5 billion CFU

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Probiotic supplement
Each sachet contains:

Probiotic blend equivalent to 8,5 X 10^9 CFU	**126,51 mg**
Consists of:	
Lactobacillus plantarum	4,61 x 10^9 CFU
Bifidobacterium animalis	3,19 x 10^9 CFU
Lactobacillus acidophilus	4,25 x 10^8 CFU
Lactobacillus rhamnosus	1,28 X 10^8 CFU
Streptococcus thermophilus	1,28 x 10^8 CFU
Lactobacillus casei	1,06 x 10^8 CFU
Bifidobacterium breve	2,13 x 10^7 CFU
Bifidobacterium longum	2,13 x 10^7 CFU
Fructo-oligosaccharide	714,84 mg
Galacto-oligosaccharide	1,5 mg
Arabic Gum	315,15 mg
Arabinogalactan (*Larix laricina* (Du Roi) K. Koch)	1,5 mg
Manapol® (*Aloe vera* (L.) Burm.f. (Aloe) [inner leaf gel, 415:1 extract, providing 622.5 mg fresh herb equivalent])	1,5 mg
Tragacanth (*Astragalus gummifer* Labill.)	1,5 mg

Excipients with known effect:
Contains sugar: Each sachet contains 0,15 mg lactose monohydrate, 0,15 mg glucose and 0,15 mg galactose.

Contains sugar alcohol: Each sachet contains 195 mg xylitol.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Powder.
Beige coloured granules with a slightly sweet, yoghurt flavour.

MANNATECH®

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

When ingested on a regular basis, probiotics in GI-PROBALANCE should improve or normalise the microbial balance in the intestines and thereby improve the functioning of the digestive tract/gut.

4.2 Posology and method of administration

Posology

Adults

Take one sachet per day with or without food and/or liquid. Do not use with hot liquids. Do not take GI-PROBALANCE powder if the sachet is damaged.

GI-PROBALANCE and antibiotic and/or antifungal medicines should be separated by at least 2 hours.

Method of administration

Oral administration.

4.3 Contraindications

- Hypersensitivity to any of the active ingredients or to any of the excipients listed in section 6.1.
- Patients with immune-compromised conditions (e.g. acquired immunodeficiency syndrome (AIDS), lymphoma, patients undergoing long-term corticosteroid treatment).
- 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

- GI-PROBALANCE might interfere with blood glucose control during and after surgical procedures. Patients should be advised to discontinue GI-PROBALANCE at least 2 weeks prior to any surgical procedures.
- Patients with faecal impaction or symptoms such as abdominal pain, nausea, vomiting, bloody diarhoea or fever should consult a health care provider prior to use.
- If abdominal pain, cramps, spasms and/or diarrhoea is experienced after taking GI-PROBALANCE, patients should stop taking GI-PROBALANCE or reduce the dose.

- Patients should stop use and consult a health care provider if symptoms of digestive upset (e.g. diarrhoea) occur, worsen and/or persist beyond 3 days.
- Patients should consult a health care provider prior to use if they have ulcerative colitis, short bowel syndrome, valvular heart disease or a kidney disorder.

Glucose, galactose and lactose monohydrate
GI-PROBALANCE contains lactose monohydrate, glucose and galactose. Patients with rare hereditary problems of galactose intolerance, e.g. galactosaemia, total lactase deficiency, or glucose-galactose malabsorption should not take GI-PROBALANCE.

4.5 Interaction with other medicines and other forms of interaction

Antibiotic and antifungal medicines:
Concomitant use of certain antibiotic and antifungal medicines with GI-PROBALANCE may decrease its effectiveness. The administration of antibiotic and/or antifungal medicines and GI-PROBALANCE should be separated by at least 2 hours.

Anticoagulant or antiplatelet medicines:
GI-PROBALANCE may potentiate the effects of anticoagulant and antiplatelet medicines or herbal supplements with blood thinning effects.

Patients taking 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-PROBALANCE contains *Aloe vera* which is contraindicated during pregnancy and lactation (see section 4.3)

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Immune system disorders:
Less frequent: hypersensitivity reactions.

Gastrointestinal disorders:
Less frequent: bloating, flatulence.

Skin and subcutaneous tissue disorders:
Less frequent: rash, itching.

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of GI-PROBALANCE is important. It allows continued monitoring of the benefit/risk balance of GI-PROBALANCE. 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 overdosage, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES
Category and class: D33.7 Combination product.

Mechanism of action:
Bifidobacteria are anaerobic, rod-shaped, Gram-positive bacteria that normally colonise the human colon. Bifidobacteria belong to a group of bacteria called lactic acid bacteria.

Lactobacilli are lactic acid-producing, Gram-positive rods that are obligate and facultative anaerobes. Lactobacilli stabilise the mucosal barrier and decrease intestinal permeability.

Bifidobacteria and lactobacillus are considered beneficial bacteria and taken for the purpose of re-colonising areas where they normally would occur.

Streptococcus thermophilus is a lactic acid-producing bacterium that facilitates the digestion of lactose in milk products and decreases the symptoms of malabsorption.

Aloe has anti-inflammatory, antioxidant, detoxification and immune-boosting properties.

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

Larch arabinogalactan has immune-boosting properties.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
silicon dioxide,
vitamin C,
xylitol (E967),
yoghurt flavour powder,
yoghurt powder (containing milk solids, glucose and dextrin).

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
18 months.

6.4 Special precautions for storage
Store at or below 25 °C, in a dry place.

6.5 Nature and contents of container
PET/PE/Alu sachets containing 1,5 g powder.

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
August 2021

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