

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS 50

Category D: Complementary medicine.

Discipline: Health Supplement

34.12 Multiple substance formulation

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

### GI SUSTAIN™, 400 g, 840 g & 1,2 kg Powder

READ ALL OF THIS LEAFLET CAREFULLY BECAUSE IT CONTAINS IMPORTANT INFORMATION FOR YOU

- **GI SUSTAIN™** is available without a doctor's prescription.
- Nevertheless, you still need to use **GI SUSTAIN™** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **GI SUSTAIN™** with any other person.
- Ask your pharmacist or healthcare professional if you need more information or advice.

#### WHAT IS IN THIS LEAFLET

- What **GI SUSTAIN™** is and what it is used for.
- What you need to know before you take **GI SUSTAIN™**.
- How to take **GI SUSTAIN™**.
- Possible side effects.
- How to store **GI SUSTAIN™**.
- Contents of the pack and other information.

#### WHAT GI SUSTAIN™ IS AND WHAT IT IS USED FOR

**GI SUSTAIN™** is formulated to provide nutritional support for the gastrointestinal tract. This formula includes a blend of readily digestible macronutrients and prebiotic nutrients, which may support the maintenance of a balanced gut environment.

#### BEFORE YOU TAKE GI SUSTAIN™

If you are taking any chronic medication, do not use this product without consulting your healthcare provider. Do not take **GI SUSTAIN™** if you are hypersensitive (allergic) to any of the ingredients. If you have allergies, be sure to check with your healthcare professional before taking this supplement.

**Surgery:** Stop taking **GI SUSTAIN™** at least two weeks before scheduled surgery. **Antibiotics:** Take your antibiotics 2 hours before or after taking **GI SUSTAIN™**. **Laboratory tests:** Active ingredients in **GI SUSTAIN™** may alter the results of tests. Please tell your healthcare practitioner that you are taking **GI SUSTAIN™** before having any laboratory tests.

This medicine has not been evaluated by the SAHPRA for quality, safety, or intended use.

#### PREGNANCY AND BREASTFEEDING

Safety during pregnancy and breastfeeding has not been established. 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 healthcare practitioner for advice before taking this supplement.

#### WHAT GI SUSTAIN™ CONTAINS

Each one (1) scoop (24,5 g) of **GI SUSTAIN™** contains the following actives:

Rice Protein	6,5 g	L-Cysteine (as L-cysteine HCl)	12,5 mg
Isomaltoligosaccharides	1,7 g	Vitamin B3 (as niacinamide)	5 mg
Calcium citrate (providing elemental calcium 100 mg)	488 mg	Zinc (as zinc gluconate)	3,75 mg
Dipotassium phosphate (providing elemental potassium 115 mg and elemental phosphorus 44 mg)	261,5 mg	Iron (as ferrous fumarate)	1,8 mg
L-Glutamine	250 mg	Vitamin B6 (as pyridoxine HCl)	0,35 mg
Dicalcium phosphate (providing elemental calcium 20 mg and elemental phosphorus 15 mg)	68 mg	Vitamin B2 (as riboflavin)	0,3 mg
Magnesium (as magnesium citrate)	60 mg	Copper (as copper gluconate)	0,25 mg
Vitamin C (as ascorbic acid)	52 mg	Vitamin B1 (as thiamine HCl)	0,25 mg
Vitamin B5 (as D-calcium pantothenate)	50 mg	Vitamin A (as beta-carotene)	350 µg
Glycine	50 mg	Vitamin A (as retinyl palmitate)	225 µg
DL-Methionine	50 mg	Folate (as calcium L-5-methyltetrahydrofolate)	70,5 µg
L-Lysine (as L-lysine HCl)	17,5 mg	Vitamin H (as biotin)	52,5 µg
L-Threonine	17 mg	Chromium (as chromium picolinate)	37,5 µg
Vitamin E (as d-alpha-tocopheryl acetate)	16,75 mg	Vitamin B12 (as methylcobalamin)	1,05 µg
		Vitamin D (as cholecalciferol)	0,6 µg

**Inactive Ingredients:** Apple fibre, gum acacia, medium-chain triglycerides, natural flavours, olive oil, rice maltodextrin and silica.

**Contains Sweetener:** Rice syrup solids 3,7 g

**This product is dairy, gluten free and non-GMO.**

#### IMPORTANT INFORMATION ABOUT SOME OF THE INGREDIENTS OF GI SUSTAIN™

**GI SUSTAIN™** contains Rice syrup solids which may have an effect on the control of your blood sugar if you have diabetes mellitus.

#### DRIVING AND USING MACHINES

It is not always possible to predict to what extent **GI SUSTAIN™** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in activities relating to requiring mental alertness, judgement and/or sound co-ordination and vision e.g. driving, riding, flying, sailing, operating machines/equipment, until they are aware of the measure to which **GI SUSTAIN™** may affect you.

#### TAKING OTHER MEDICINES WITH GI SUSTAIN™

Complementary medicine products contain ingredients which may interact with some medication. If you are taking any chronic medication, do not use this product without consulting your medical practitioner.

Document Reference: GISUS.PIL.CMP 12-24



#### HOW TO TAKE GI SUSTAIN™

Do not share medicines prescribed for you with any other person. Always take **GI SUSTAIN™** exactly as described in this leaflet, or as your doctor, healthcare provider has instructed you. You should check with your doctor, pharmacist or healthcare provider if you are unsure.

#### Directions for use:

Blend, shake, or briskly stir about two (2) level scoops into 120 ml of chilled water or juice twice daily or as directed by your healthcare practitioner.

For highly sensitive individuals, consider reducing consumption to ½ to 1 scoop with 80 ml of chilled water or juice twice daily during the first 3 to 4 days before starting a full daily dose.

**Do not take more than the recommended dose.**

#### IF YOU TAKE MORE GI SUSTAIN™ THAN YOU SHOULD

In the event of overdose, consult your doctor, pharmacist. Should none of these be available, contact the nearest hospital or poison control centre.

#### IF YOU FORGET TO TAKE GI SUSTAIN™

Do not take a double dose to make up for a missed dose.

#### POSSIBLE SIDE EFFECTS

**GI SUSTAIN™** may have side effects.

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: Liver disease, Bipolar disorder, Monosodium glutamate (MSG) sensitivity, Seizures, Heart conditions, Hormone-sensitive conditions such as breast cancer, uterine cancer, ovarian cancer, endometriosis, or uterine fibroids, High blood pressure, A muscle condition caused by nerve problems (hypertonia), Low potassium levels in the blood (hypokalaemia), Kidney disease, Intestinal conditions such as Crohn disease, ulcerative colitis, or obstruction. If you are taking the following medication, please consult with your healthcare practitioner before taking: Medications used to prevent seizures (Anticonvulsants), Digoxin (Lanoxin), Oestrogens, Water pills (Loop diuretics), high blood pressure (Antihypertensive drugs), anti-inflammatories (Corticosteroids), Warfarin (Coumadin), Water pills (Diuretic drugs), Midazolam (Versed), diabetes (Antidiabetes drugs), Stimulant laxatives. If any of the following happens, stop using **GI SUSTAIN™** and tell your doctor or go to the casualty department at your nearest hospital:

- Allergic reactions – rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

These are all very serious effects. If you have them, you may have had a serious reaction to **GI SUSTAIN™**. You may need urgent medical attention or hospitalisation.

Side effects that usually do not require medical attention (report to your healthcare professional if they continue):

- nausea/vomiting, constipation, loss of appetite, mental/mood changes, unusual tiredness.

Not all side effects and interactions reported for **GI SUSTAIN™** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice. If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or healthcare professional.

#### REPORTING OF SIDE EFFECTS

If you experience side effects, talk to your doctor, pharmacist or other healthcare professional. You can also report side effects to SAHPRA via "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **GI SUSTAIN™**.

#### STORAGE AND DISPOSING OF GI SUSTAIN™

Store all medicines out of the reach of children.

Store in a cool, dark place, below 25 °C.

Protect from direct sunlight and heat.

Store in the original packaging.

Do not use after the expiry date stated on the bottle.

Do not use **GI SUSTAIN™** if you notice visible signs of deterioration.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

#### PRESENTATION OF GI SUSTAIN™

PBMS 11 white jar HDPE with 85 mm white lid, with pressure seal and a 50 ml scoop

#### IDENTIFICATION OF GI SUSTAIN™

Light tan powder.

#### REGISTRATION NUMBER –

To be allocated by SAHPRA upon registration.

#### ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION

Scan QR code.

#### THIS LEAFLET WAS LAST REVISED ON

19 December 2024

#### NAME AND ADDRESS OF REGISTRATION HOLDER

Distributed by:

Amipro Advanced Development Products (Pty) Ltd  
Unit 3, Eastgate Business Park, 1 South Road, Eastgate Extension,  
Sandton, 2146, Tel: 011-802-8101



## PASIËNT INLIGTINGSBLAD

### SKEDULERINGSSTATUS <sup>50</sup>

Kategorie D: Komplementêre medisyne.  
Disipliene: Gesondheidsaanvulling  
34.12 Meervoudige Bestandeel Formulase

HANDELSNAAM EN DOSEERVORM,

## GI SUSTAIN™, 400 g, 840 g & 1,2 kg Poer

### LEES HIERDIE INLIGTINGSBLAD NOUKEURIG, WANT DIT BEVAT BELANGRIKE INLIGTING VIR U

- **GI SUSTAIN™** is beskikbaar sonder doktersvoorskrif.
- U moet steeds **GI SUSTAIN™** versigtig gebruik om die beste resultate daaruit te kry.
- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
- Moenie **GI SUSTAIN™** met enige ander persoon deel nie.
- Vra jou apteker of gesondheidsorgpraktysin of jy meer inligting of advies benodig.

### WAT IS IN HIERDIE INLIGTINGSBLAD

- Wat **GI SUSTAIN™** is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy **GI SUSTAIN™** neem.
- Hoe om **GI SUSTAIN™** te neem.
- Moontlike nuwe-effekte.
- Hoe om **GI SUSTAIN™** te bêre.
- Inhoud van die pak en ander inligting.

### WAT IS GI SUSTAIN™ KAPSULES EN WAARVOOR WORD DIT GEBRUIK

**GI SUSTAIN™** is geformuleer om voedingsondersteuning vir die spysverteringskanaal te bied. Hierdie formule bevat 'n mengsel van maklik verteerbare makrovoedingstowwe en prebiotiese voedingstowwe, wat die instandhouding van 'n gebalanseerde dermorgewing kan ondersteun.

### SWANGERSKAP EN BORSVOEDING

Veiligheid tydens swangerskap en borsvoeding is nie vasgestel, raadpleeg u gesondheidsorgpraktysin voor gebruik. As u swanger is of borsvoed, dink dat u swanger is of beplan om 'n baba te hê, raadpleeg u gesondheidsorgpraktysin voordat u hierdie aanvulling neem.

### WAT GI SUSTAIN™ BEVAT

**Eke een (1) skep (24,5 g) GI SUSTAIN™ bevat die volgende aktiewe:**

Rys proteïen	6,5 g	L-isteïen (as L-isteïen HCl)	12,5 mg
Isomalto-oligosakkariede	1,7 gram	Vitamiën B3 (as niacinamide)	5 mg
Kalsiumitraat (die verskaffing van elementêre kalsium 100 mg)	488 mg	Sink (as sinkglukonaat)	3,75 mg
Dikalsiumfosfaat (wat elementêre kalsium 115 mg en elementêre fosfor 44 mg verskaf)	261,5 mg	Yster (as ysterhoudende fumarat)	1,8 mg
L-glutamiën	250 mg	Vitamiën B6 (as piridoksiën HCl)	0,35 mg
Dikalsiumfosfaat (wat elementêre kalsium 20 mg en elementêre fosfor 15 mg verskaf)	68 mg	Vitamiën B2 (as riboflaviën)	0,3 mg
Magnesium (as magnesiumsitraat)	60 mg	Koper (as koperglukonaat)	0,25 mg
Vitamiën C (as askorbien suur)	52 mg	Vitamiën B1 (as tiamien HCl)	0,25 mg
Vitamiën B5 (as D-kalsiumpanthoënaat)	50 mg	Vitamiën A (as beta-karoteen)	350 µg
Glisiën	50 mg	Vitamiën A (as retinylpalmitaat)	225 µg
DL-metioniën	50 mg	Folfaat (as kalsium L-5-metiltetrahidrofolaat)	70,5 µg
L-lysiën (as L-lysiën HCl)	17,5 mg	Vitamiën H (as biotiën)	52,5 µg
L-Threoniën	17 mg	Chroom (as chroompikolinnat)	37,5 µg
Vitamiën E (as α-tokoferiëlaatsaat)	16,75 mg	Vitamiën B12 (as metielkobalamiën)	1,05 µg
		Vitamiën D (as cholecalciferol)	0,6 µg

**Onaktiewe bestanddele:** Appelvesel, akasiagam, feriumketting trigliseriede, natuurlike geure, olyfolye, rismaldekstrien en silika.

**Bevat versoeter:** Rysstroop vaste stowwe 3,7 g

Hierdie produk is suiwel, glutenvry en nie-GGO.

### BELANGRIKE INLIGTING OOR SOMMIGE VAN DIE BESTANDELE VAN GI SUSTAIN™

**GI SUSTAIN™** bevat rysstroop vaste stowwe wat 'n effek op die beheer van jou bloedsuiker kan hê as jy diabetes mellitus het.

### VOORDAT JY GI SUSTAIN™ NEEM

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktysin te raadpleeg nie. Moenie **GI SUSTAIN™** neem as jy hipersensitief (allergies) is vir enige van die bestanddele nie. As jy allergiese het, maak seker dat jy met jou gesondheidsorgpraktysin gaan voordat jy hierdie aanvulling neem. **Chirurgie:** Hou op om **GI SUSTAIN™** ten minste twee weke voor die geskeduleerde operasie te neem. **Antibiotika:** Neem jou antibiotika 2 ure voor of nadat jy **GI SUSTAIN™** geneem het.

**Laboratoriotoets:** Aktiewe bestanddele in **GI SUSTAIN™** kan die resultate van toets verander. Vertel asseblief jou gesondheidsorgpraktysin dat jy **GI SUSTAIN™** neem voordat jy enige laboratoriotoets ondergaan.

Hierdie medisyne is nie deur die SAHPRA geëvalueer vir kwaliteit, veiligheid of beoogde gebruik nie.

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### BESTUUR EN GEBRUIK VAN MASIËNE

Dit is nie altyd moontlik om te voorspel in watter mate **GI SUSTAIN™** die daaglikse aktiwiteite van 'n pasiënt kan belemmer nie. Pasiënte moet seker maak dat hulle nie betrokke raak by aktiwiteite wat verband hou met die verlies van verstandelike waaksaamheid, oordeel en/of gesonde koördinasie en visie nie, byvoorbeeld bestuur, ry, vlieg, seil, bedryfmasjiene/toerusting, totdat hulle bewus is van die mate waartoe **GI SUSTAIN™** jou beïnvloed.

### NEEM VAN ANDER MEDISYNE SAAM MET GI SUSTAIN™

Komplementêre medisyne produkte bevat bestanddele wat met sommige medisyne 'n interaksie kan hê. As jy enige chroniese medisyne gebruik, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktysin te raadpleeg nie.

### HOE OM GI SUSTAIN™ TE NEEM

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Neem altyd **GI SUSTAIN™** presies soos beskryf in hierdie inligtingsblad, of soos u dokter, gesondheidsorgpraktysin voorgeskryf het. Raadpleeg jou dokter, apteker of gesondheidsorgpraktysin as jy onseker is.

### Aanwysings vir gebruik:

Meng, skud of roer ongeveer twee (2) vlakke lepels twee keer per dag in 120 ml verkoelde water of sap of soos voorgeskryf deur jou gesondheidsorgpraktysin.

Vir hoog sensitiewe individue, oorweeg dit om verbruik te verminder tot ½ tot 1 lepel met 80 ml verkoelde water of sap twee keer per dag gedurende die eerste 3 tot 4 dae voordat 'n volle daaglikse dosis begin.

### Moenie meer as die aanbevole dosis neem nie.

### AS JY MEER GI SUSTAIN™ NEEM AS WAT JY MOET

In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie hiervan beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

### AS JY VERGEET OM GI SUSTAIN™ TE NEEM

Moenie 'n dubbele dosis neem om op te maak vir 'n dosis wat oorgeslaan is nie.

### MOONTLIKE NUWE-EFFEKTE

**GI SUSTAIN™** kan nuwe-effekte hê.

Indien jy enige van die volgende gegdiagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktysin voor gebruik: Lewersiekte, Bipolêre versteuring, Mononatriumglutamaat (MSG) sensitiwiteit, Aanvalle, Harttoestande, Hormoon sensitiewe toestande soos borskanker, baarmoederkanker, eierstokkanker, endometriose, of baarmoederfibroïede, hêe bloeddruk, 'n Spiertoestand wat veroorsaak word deur senuweeprobleme (hipertonie), Lae kaliumvlakke in die bloed (hipokalemie), Niersiekte, dermtoestande soos Crohn-siekte, uiseriatieve kolitis of obstruksie.

As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidsorgpraktysin voordat jy neem: medisyne wat gebruik word om aanvalle te voorkom (Antikonvulsante), Digoksiën (Lanoxin), Estrogeen, Waterpille (Loop diuretika), hêe bloeddruk (Antihipertensiewe middels), anti-inflammatoriese middels (kortikosteroïede), Warfarin (Coumadin), Waterpille (Diuretika), Midazolam (Versed), Diabetes (Antidiabetes middels), Stimulerende laksemiddels. As enige van die volgende gevege, hou op om **GI SUSTAIN™** te gebruik en vertel jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- Allergiese reaksies- uitslag, jeuk / swelling (veral van die gesig / tong / keel), erge duiseligheid, probleme met asemhaling;

Dit is alles baie ernstige gevege. As jy dit het, het jy dalk 'n ernstige reaksie op **GI SUSTAIN™** gehad. Jy mag dalk dringende mediese hulp of hospitalisasie nodig hê.

Nuwe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteer aan u gesondheidsorgpraktysin as dit voortduur):

- naarheid / braking, hardlywighede, verlies aan eetlust, geestelike / gemoedsveranderinge, ongewone moegheid.

Nie alle nuwe-effekte en interaksies wat vir **GI SUSTAIN™** gerapporteer word, is by hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid vererger of as jy enige nadelige effekte ervaar tydens die gebruik van hierdie medisyne, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgpraktysin vir raad. As jy enige nuwe-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktysin in kennis.

### AANMELDING VAN NUWE-EFFEKTE

As jy enige nuwe-effekte ervaar, praat met jou dokter, apteker of ander gesondheidsorgpraktysin. U kan ook nuwe-effekte aan SAHPRA rapporteer via "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind word onder SAHPRA se publikasies:

<https://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van **GI SUSTAIN™**.

### HOE OM GI SUSTAIN™ TE BÊRÊ

Bêre alle medisyne buite bereik van kinders.

Bêre in 'n koel, donker plek, onder 25°C.

Beskerm teen direkte sonlig en hitte.

Bêre in die oorspronklike verpakking.

Moet nie gebruik word na die vervaldatum wat op die bottel aangedui word nie.

Moenie **GI SUSTAIN™** gebruik as u sigbare tekens van agteruitgang opmerk nie.

Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

### AANBEWELING VAN GI SUSTAIN™

PBMS 11 wit pot HDPE met 85 mm wit deksel, met drukseël en 'n 50 ml skeppie

### IDENTIFIKASIE VAN GI SUSTAIN™

Ligte bruin poer.

### REGISTRASIONOMMER

Om deur SAHPRA toegeken te word by registrasie.

### TOEGANG TOT DIE OOREENSTEMMENDE PROFESSIONELE INLIGTING

Skandeer QR-kode.

### HIERDIE INLIGTINGSBLAD IS LAAS HERSIEN OP

19 Desember 2024

### NAAM EN ADRES VAN REGISTRASIEHOUER

Versprei deur:

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