

**PROFESSIONAL INFORMATION** 
 **D 33.7 Combination Product. Complementary medicine.** 

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use. Health supplements are intended only to complement health or supplement the diet.

**SCHEDULING STATUS:** **S0**

 **1. NAME OF THE MEDICINE** 

BIOGEN DIGESTIVE ENZYMES (Vegetable capsules).

 **2. QUALITATIVE AND QUANTITATIVE COMPOSITION** 
 **EACH VEGETABLE CAPSULE CONTAINS:** 

Zingiber officinale (Ginger) [Root Powder]	150,00 mg
Capsicum annum L. (Cayenne Pepper) [Fruit powder]	100,00 mg
Betaine hydrochloride	100,00 mg
Multi-enzyme blend containing:	50,00 mg
Amylase	1,750 SKB
Protease	7,778 HUT
Lactase	83 ALU
Cellulase	155 CU
Lipase	345 LU
Invertase	61 SU
Diastase	125 DP

Sugar Free

For the full list of excipients, see section 6.1.

 **3. PHARMACEUTICAL FORM** 

Vegetable Capsules.

 **4. CLINICAL PARTICULARS** 
 **4.1 Therapeutic indications** 

BIOGEN DIGESTIVE ENZYMES, assists with digestion and digestive discomfort.

 **4.2 Posology and method of administration** 
 **Adults (18 years and older)** 

Take 1-2 (one to two) vegetable capsules with a meal, or as recommended by your healthcare provider. Consult a health care provider for prolonged use.

The safety and efficacy of BIOGEN DIGESTIVE ENZYMES in children has not yet been established. Please consult a healthcare provider prior use.

 **4.3 Contraindications** 

- If you have a hypersensitivity to any of the ingredients or excipients listed in 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, hemorrhoids or diarrhea.

 **4.4 Special warnings and precautions for use** 

Special care should be taken with BIOGEN DIGESTIVE ENZYMES.

If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine.

Please take note of the following:

- Consult a healthcare provider if symptoms develop, worsen or persist.
- Consult a relevant health care provider prior to use if you have a peptic ulcer or excess stomach acid.
- Consult a healthcare provider prior to use if you have faecal impaction or symptoms such as abdominal pain, nausea, vomiting or fever.
- Consult a relevant health care provider before use if you have malabsorption or other GIT ailments or are having surgery; or are taking blood thinners, antibiotics or anti-inflammatory medication.
- Consult a healthcare provider prior to use if you have a kidney disorder, or are taking cardiac medications (e.g. cardiac glycosides or antiarrhythmic medications).
- Consult a healthcare provider prior to use if you are taking thiazide diuretics, corticosteroids, licorice root, or other medications or health products that may aggravate electrolyte imbalance.
- Reduce dose or stop use if you experience abdominal pain, cramps, spasms and/or diarrhea.
- Consult a relevant health care provider before use if you are pregnant or breastfeeding, or for use beyond four (4) weeks.
- Consult a relevant health care provider before use if you have diabetes.

Nutritional supplementation should not replace a balanced diet. Do not exceed the recommended dose without consulting a healthcare provider.

 **4.5 Interaction with other medicines and other forms of interaction** 
 **Interactions with Medicines** 

- Ginger powder may have antiplatelet effects and may increase the risk of bleeding if used with anticoagulant or antiplatelet medication.
- Taking ginger powder with antidiabetes drugs might increase the risk of hypoglycemia.
- Ginger powder as in BIOGEN DIGESTIVE ENZYMES, taking ginger powder with calcium channel blockers might increase the risk of hypotension.
- Ginger powder might decrease cyclosporine levels.
- Ginger powder might increase levels of losartan and the risk of hypotension, increase levels of metronidazole, NIFEDIPINE (Procardia).
- Ginger powder may have antiplatelet effects and increase the risk of bleeding if used with nifedipine.
- Ginger powder and capsaicin might increase the risk of bleeding if used with anticoagulant or antiplatelet medication, such as with phenprocoumon, and warfarin.
- Theoretically, capsaicin may increase the risk of bleeding if used with anticoagulant or antiplatelet drugs.
- Taking capsaicin with aspirin might reduce the bioavailability of aspirin.
- Taking capsaicin with ciprofloxacin might increase levels and adverse effects of ciprofloxacin.
- Capsicum with theophylline might increase the levels and adverse effects of theophylline.

 **Interactions with Diseases / Impairments** 

- Ginger powder might increase the risk of bleeding, caution is advised. Ginger powder has antiplatelet, hypoglycemic effects, and might increase the risk of bleeding or interfere with blood glucose control if used perioperatively. Patients are advised to discontinue ginger powder at least 2 weeks before elective surgical procedures.

 **Interactions with Foods** 

- Vitamins, minerals and nutrients obtained from other sources should be taken into account when prescribing / suggesting BIOGEN DIGESTIVE ENZYMES.

 **4.6 Fertility, pregnancy and lactation** 

Safety in pregnancy and lactation has not been established and is contraindicated in pregnancy (see section 4.3).

 **4.7 Effects on ability to drive and use machines** 

No studies on the effects on the ability to drive or use machinery have been performed. It is advised that patients taking BIOGEN DIGESTIVE ENZYMES should not drive or operate machinery until they are reasonably certain that it does not adversely affect their ability to drive or operate machinery.

 **4.8 Undesirable effects** 

Orally, the ingredients in BIOGEN DIGESTIVE ENZYMES is well-tolerated.

 **4.8 a Summary of adverse reactions** 

Gastrointestinal disorders:

*Frequent:* Mild gastrointestinal symptoms have been reported, including nausea, vomiting, bloating, diarrhea, abdominal discomfort, flatulence, constipation, and loss of appetite.

Dermatologic:

*Frequency unknown:* Skin irritation, skin rash pruritus, and urticaria.

 **4.8 b Description of selected adverse reactions** 

BIOGEN DIGESTIVE ENZYMES may cause several adverse reactions, including nausea, vomiting, bloating, diarrhea, epigastric pain, abdominal colic or discomfort, dyspepsia, dysgeusia, flatulence, constipation, and loss of appetite. Aloe may cause abdominal pain, cramps, and diarrhea.

 **4.8 c Paediatric Population** 

BIOGEN DIGESTIVE ENZYMES is not recommended for use in children under the age of 18 years.

 **4.8 d Other special populations** 

No clinical data are available on the effects of BIOGEN DIGESTIVE ENZYMES on other special populations.

 **4.9 Overdose** 

Side effects listed in section 4.8 can be precipitated and/ or be of increased severity.

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

 **Reporting of suspected adverse reactions** 

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

 **5. PHARMACOLOGICAL PROPERTIES** 
 **5.1 Pharmacodynamic properties** 

Mechanism of action:

*Ginger powder:* Traditionally used for stomach and gastrointestinal ailments.

*Cayenne Pepper:* Capsaicin, a constituent of capsaicin, might have gastroprotective effects.

*Multiple Enzyme blend:* proprietary blend of five specific enzymes, viz.  $\alpha$ -amylase (starch digestive enzyme), protease (protein digestive enzyme), lipase (Fat digestive enzyme), cellulase (cellulose hydrolyzing enzyme), and lactase (lactose hydrolyzing enzyme). This provides optimal digestion of all the macromolecules.

 **5.2 Pharmacokinetic properties** 

*Ginger powder:*

*Absorption:* Following consumption of ginger powder, at one hour after administration of 2 grams of ginger powder.

*Distribution:* 6-Ginger powderol, 8-ginger powderol, 10-ginger powderol, and 6-shogaol and their metabolites lacked evidence of accumulation in plasma or colon tissues following multiple daily doses of ginger powder. In an in vitro model, 6-ginger powderol, 8-ginger powderol, and 6-shogaol were able to cross the blood brain barrier.

*Metabolism:* Conjugates of the ginger powderols and 6-shogaol are usually glucuronide or sulfate conjugates, and not mixed conjugates. However, mixed conjugates of some constituents do occur.

*Elimination:* In human plasma, the half-life of 6-ginger powderol, 8-ginger powderol, 10-ginger powderol, and 6-shogaol has been estimated to be 0.5-3 hours.

*Cayenne Pepper:*

*Absorption:* Taking capsaicin 5 grams results in a maximum concentration of capsaicin of 2.47 ng/mL at about 47 minutes after ingestion.

*Metabolism:* In vitro evidence suggests that capsaicinoids, which are components of dried chili peppers, are metabolized by cytochrome P450 2E1 (CYP2E1) enzymes.

*Excretion:* Capsaicin 5 grams taken by mouth had an elimination half-life of approximately 25 minutes.

*Distribution/ Metabolism/ Excretion:*

No clinical data are available on the effects of BIOGEN DIGESTIVE ENZYMES.

 **Preclinical safety data** 

When used orally and appropriately in adults, BIOGEN DIGESTIVE ENZYMES is recognized as possibly safe.

 **6. PHARMACEUTICAL PARTICULARS** 
 **6.1 List of excipients** 

Vegetable capsules, microcrystalline cellulose, maltodextrin, and magnesium stearate.

 **6.2 Shelf Life** 

24 Months.

 **6.3 Special precautions for storage** 

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

Do not use after expiry date.

Keep the container tightly closed.

Protect from light.

KEEP OUT OF REACH OF CHILDREN.

 **6.4 Nature and contents** 

The container is a 250 ml PET container.

The cap is a white plastic cap with a tamper evident seal.

 **6.5 Special precautions for disposal** 

No special requirements.

 **7. HOLDER OF CERTIFICATE OF REGISTRATION** 

Biogen.

23 Stag Rd,

Glen Austin,

South Africa.

 **8. REGISTRATION NUMBER** 

Will be allocated by SAHPRA upon registration.

 **9. DATE OF FIRST AUTHORISATION** 

Will be allocated by SAHPRA upon registration.

5415P01

<b>JOB:</b> BPS_Biogen Digestive Enzymes_60s	<b>SIZE:</b> 210mm x 255mm
<b>STOCK:</b> Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>	
<b>COLOURS:</b>	<b>FINISHING:</b>
<input checked="" type="checkbox"/> K <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot	<input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss
<input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot	<input type="checkbox"/> Spot UV <input type="checkbox"/> Doming <input type="checkbox"/> Embossing
<b>PLEASE CHECK CAREFULLY</b> Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.	