

PATIENT INFORMATION LEAFLETSCHEDULING STATUS: PRODUCT NAME
BIOGEN DIGESTIGAST dropsAngelica, Caraway, Ceylon cinnamon, German chamomile, Ginger, Lemon balm, Licorice, Milk thistle, Peppermint. Sugar free.
Contains ethyl alcohol: 31 % v/v

Complementary Medicine: D 33.6 Western Herbal Medicine. Discipline-Specific Traditional Claims.

Health supplements are intended only to complement health or supplement the diet.

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

Read all of this leaflet carefully because it contains important information for you.

BIOGEN DIGESTIGAST is available without a doctor's prescription, for you to maintain your health.

Nevertheless, you still need to use BIOGEN DIGESTIGAST carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share BIOGEN DIGESTIGAST with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

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

1. What BIOGEN DIGESTIGAST is and what it is used for

BIOGEN DIGESTIGAST, a herbal tincture with 9 botanical extracts for the relief of symptoms related to gastric and abdominal discomfort like; abdominal pain & cramps, heartburn, flatulence, chronic constipation, nausea and irritable bowel syndrome (IBS).

2. What you need to know before you take BIOGEN DIGESTIGAST

Do not take BIOGEN DIGESTIGAST:

- If you are hypersensitive (allergic) to Angelica, Caraway, Ceylon cinnamon, German chamomile, Ginger, Lemon balm, Licorice, Milk thistle, Peppermint, or to any of the other ingredients in BIOGEN DIGESTIGAST (listed in section 6).
- If you have hiatal hernia - Peppermint may worsen this condition.
- If you have hypokalaemia (low potassium levels) - Licorice may cause/exacerbate hypokalaemia.
- If you have high blood pressure - Licorice may increase/worsen blood pressure levels.
- If you have kidney disorders - Licorice may negatively affect kidney function.
- If you have cardiovascular (heart) disorders - Licorice may worsen heart disease.
- If you are pregnant or breastfeeding, do not use BIOGEN DIGESTIGAST.

Warnings and precautions

- Use with caution if you have hemochromatosis (iron overload) - Caraway may increase the intestinal absorption of iron.
- Use with caution if you have low blood pressure (hypotension), or if you are taking antihypertensive medication - Ceylon cinnamon may lower blood pressure.
- Use with caution if you have low blood glucose levels (hypoglycaemia), or taking anti-diabetic medication - Ceylon cinnamon, Ginger, and Caraway may affect blood glucose levels.
- Discontinue use at least 2 weeks prior to elective surgical procedures.
- Use with caution if you have hormone sensitive conditions - German chamomile, Licorice and Milk thistle may have estrogenic/antiestrogenic effects.
- Use with caution if you have bleeding conditions - Ginger might increase the risk of bleeding.
- Licorice may worsen muscle overactivity (hypertonia).
- Avoid prolonged exposure to sunlight, ultraviolet therapy/ultraviolet light.
- Use with caution if you suffer from anaemia (lack of red blood cells).
- Use with caution if you have gallstones.
- Use with caution if you have thyroid disease.

Children and adolescents

Angelica, Caraway, Ceylon cinnamon, and Licorice - Insufficient reliable information.

German chamomile, Ginger, Lemon balm, Milk thistle, and Peppermint - Possibly safe when used orally and appropriately in children, short-term.

Other medicines and BIOGEN DIGESTIGAST

Always tell your healthcare provider if you are taking other medicines, including complementary or traditional medicines.

Consult your doctor if you want to take BIOGEN DIGESTIGAST in combination with medicines or treatments such as:

- Antibiotics, as Licorice may theoretically increase the levels of metronidazole.
- Anticoagulants/antiplatelets (warfarin, phenprocoumon, etc.), as Ginger, German chamomile and Milk thistle may theoretically increase the risk of bleeding. Licorice may theoretically decrease the effects of warfarin.
- Antidiabetics (blood glucose lowering medication), as Ceylon cinnamon Caraway, Ginger, and Milk thistle may theoretically have additive blood glucose lowering effects.
- Antihypertensives (blood pressure lowering medication), such as calcium channel blockers, angiotensin II receptor antagonists, etc., as Ceylon cinnamon and Ginger may theoretically have additive blood pressure lowering effects. Licorice, in a dose-dependent manner, may counteract the effects of antihypertensives (increase blood pressure).
- Benzodiazepines (tranquillizers), as Licorice may theoretically decrease midazolam levels.
- Cardiac glycosides (medication increasing the force of heart contractions), as Licorice and cardiac glycoside medication (digoxin) or herbs (uzara, quassia, etc.) may theoretically increase the risk of cardiac toxicity (damaged heart muscle).
- Central nervous system (CNS) depressants, as Lemon balm, Caraway or German chamomile may theoretically have additive sedative effects.
- Chemotherapy, as Licorice may theoretically reduce the therapeutic effectiveness of chemotherapy medication (cisplatin and paclitaxel).
- Corticosteroids, such as hydrocortisone, as Licorice may theoretically increase the side effects of corticosteroids.
- Cytochrome Substrates, as Caraway dose-dependently and theoretically alters the level of medicine metabolized by cytochrome P450 1A1 (CYP1A1), and Licorice theoretically alters the level of medicine metabolized by cytochrome P450 2C9 (CYP2C9) and cytochrome P450 3A4 (CYP3A4).
- Potassium-depleting diuretics, such as chlorthalidone, chlorothiazide, furosemide, hydrochlorothiazide, etc., as Caraway and Licorice may increase the risk for hypokalaemia (below normal potassium levels).
- Loop diuretics might theoretically increase the mineralocorticoid effects (regulating salt and water balances) of Licorice by inhibiting the conversion of cortisol to cortosone.
- Glucuronidated medication (medication combined with glucuronic acid to create a more water-soluble compound), as Milk thistle may theoretically affect the metabolism/clearance of this medication.
- Hormones, as Licorice, German chamomile and Milk thistle, may theoretically influence the effects of estrogen therapy.
- Immunosuppressants, as Ginger may theoretically decrease cyclosporine levels. Milk thistle may decrease the clearance of the immunosuppressant, sirolimus.
- Laxatives, as Licorice misuse may theoretically increase the risk of potassium depletion.
- Methoxylated flavones (antioxidants reducing inflammation), as Licorice may theoretically reduce the plasma levels of supplemental methoxylated flavones.
- Opioid analgesics (pain-relieving medication), as the concomitant use of Milk thistle and morphine may theoretically affect serum morphine levels.
- Grapefruit, as it may theoretically increase the mineralocorticoid effects (salt and water balance) of Licorice.
- P-glycoprotein substrates, as Licorice theoretically may decrease the absorption of P-glycoprotein substrates.
- Protease inhibitors, as Milk thistle may theoretically affect the metabolism of indinavir, which is used to treat human immunodeficiency virus (HIV).
- Selective estrogen receptor modulators, as Milk thistle theoretically may decrease the clearance and increase levels of raloxifene (medication used to treat/prevent bone loss after menopause).
- Statins, as Milk thistle theoretically may decrease the movement of HMG-CoA reductase inhibitors (lipid-lowering statins) into the liver, and also inhibits the transport of statins from the liver into the bile for excretion.
- Thyroid hormones, as Lemon balm may interfere with thyroid hormone medication/herbs, such as levothyroxine, liothyronine and others.

Interactions with Diseases/Impairments

- Anaemia (lack of red blood cells) - Peppermint inhibits iron absorption and should be used with caution in patients with iron-deficiency.
- Bleeding conditions - Ginger may theoretically decrease platelet aggregation and increase the risk of bleeding.
- Gallstones - Menthol present in Peppermint may stimulate the gallbladder.
- Heart conditions - Licorice can worsen congestive heart failure and increase the risk of arrhythmias (heart rate/rhythm).
- Hemochromatosis (iron overload) - Caraway may increase the intestinal absorption of iron, and the risk or severity of iron overload.
- Hiatal hernia (condition where a part of the stomach pushes into the chest cavity) - Menthol relaxes the sphincter, consequently worsening hiatal hernia.
- High blood pressure (hypertension) - Licorice may increase blood pressure.
- Hormone sensitive cancers/conditions - German chamomile, Licorice and Milk thistle might have antiestrogenic/estrogenic effects - use with caution in patients with breast cancer, ovarian cancer, uterine cancer, uterine fibroids, endometriosis etc.
- Kidney disorders - Licorice may negatively affect kidney function.
- Low blood pressure (hypotension) - Ceylon cinnamon may lower blood pressure.
- Low blood sugar (hypoglycaemia) - Ceylon cinnamon, Ginger, and Caraway may lower blood sugar levels.
- Low potassium levels (hypokalaemia) - Licorice may exacerbate hypokalaemia by decreasing serum potassium levels.
- Muscle overactivity (hypertonia) - Licorice can lower potassium levels, consequently worsening muscle overactivity.
- Sexual dysfunction - Licorice might decrease libido and worsen erectile dysfunction.
- Surgical procedures - Lemon balm and German chamomile might cause additive CNS depression when combined with anaesthesia. Ginger may cause excessive bleeding, whereas Ginger and Caraway may interfere with blood glucose control. Licorice might increase blood pressure, and may as an effect, interfere with controlling blood pressure during and after surgical procedures - Discontinue use at least 2 weeks prior to elective surgical procedures.
- Thyroid dysfunction and disease - Lemon balm may theoretically alter thyroid function, and reduce thyroid hormone levels.

BIOGEN DIGESTIGAST with food and drink

- Do not take BIOGEN DIGESTIGAST with alcohol as it may increase the risk of drowsiness.
- Taking BIOGEN DIGESTIGAST with iron-containing foods may increase the absorption of iron.

Pregnancy, breastfeeding and fertility

Insufficient reliable information. Not recommended for use during pregnancy and lactation.

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 provider for advice before taking this medicine.

Driving and using machinery

It is not always possible to predict to what extent BIOGEN DIGESTIGAST may interfere with the daily activities of a patient. It is possible that BIOGEN DIGESTIGAST may affect the ability to drive or operate machinery, as is may cause drowsiness, sedation, blurred vision. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which BIOGEN DIGESTIGAST affects them.

3. How to take BIOGEN DIGESTIGAST

Do not share your medicines with any other person.

Always take BIOGEN DIGESTIGAST exactly as described in this leaflet or as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are unsure.

Take BIOGEN DIGESTIGAST drops orally.

Take before or with meals, three times a day.

Adults and children over 12 years: 20 drops (1.00 mL)

Children 6 to 12 years: 15 drops (0.75 mL)

Children 3 to 5 years: 10 drops (0.50 mL)

SHAKE WELL BEFORE USE.**If you take more BIOGEN DIGESTIGAST than you should**

Side effects listed in section 4 can be precipitated and/or be of increased severity.

Angelica, Caraway, German chamomile, Ginger, Lemon balm, Milk thistle - Insufficient reliable information. Ceylon cinnamon - Large doses of Ceylon cinnamon may cause excitation of the central nervous system (CNS), tachycardia (rapid heartbeat), and increased muscle contractions, breathing, and sweating. This may be followed by sedation.

Licorice - Due to the glycyrrhizin content in Licorice, overdosage may cause mineralocorticoid excess, or pseudohyperaldosteronism (increased urinary potassium loss, sodium and water retention, hypokalaemia, and alkalosis). Peppermint - Due to the presence of menthol, overdosage may cause severe gastro-intestinal symptoms and CNS problems.

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take BIOGEN DIGESTIGAST

Always take BIOGEN DIGESTIGAST as prescribed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

BIOGEN DIGESTIGAST can have side effects.

Not all side effects reported for BIOGEN DIGESTIGAST are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BIOGEN DIGESTIGAST, please consult your healthcare provider for advice.

Side effects associated with BIOGEN DIGESTIGAST:

Frequent:

- Photosensitivity.
- Abdominal discomfort, nausea, vomiting, heartburn, indigestion, belching, dry mouth, and perianal burning.
- Drowsiness, sedation, blurred vision.

Less frequent:

- Headache.
- Wheezing.

Frequency unknown:

- Allergic reactions - hives, eczema, skin rash, anaphylaxis, dermatitis, itchy skin, and asthma.
- Altered appetite, bloating, diarrhoea, constipation, altered taste, flatulence, epigastric pain, and gastric irritation.
- Hypersensitivity reactions.

Please report/inform your doctor or pharmacist if you notice any side effects not mentioned in this leaflet.

Reporting of side effects

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

<http://www.sahpra.org.za/Publications/Index8/>

By reporting side effects, you can help provide more information on the safety of BIOGEN DIGESTIGAST.

5. How to store BIOGEN DIGESTIGAST

- Store in a cool, dry place at or below 25 °C.
- Do not use after expiry date.
- Keep the bottle tightly closed.
- STORE ALL MEDICINE OUT OF REACH OF CHILDREN.

Return all unused BIOGEN DIGESTIGAST to your pharmacist. Do not dispose of unused BIOGEN DIGESTIGAST in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information**What BIOGEN DIGESTIGAST contains:**

The active ingredients per 1.00 mL (20 drops) are:

Cinnamomum verum J.Presl (Ceylon cinnamon) [bark] 100,00 mg

Matricaria chamomilla L. (German chamomile) [flower] 66,70 mg

Zingiber officinale Roscoe (Ginger) [rhizome] 66,70 mg

Angelica archangelica L. (Angelica) [root] 33,30 mg

Carum carvi L. (Caraway) [fruit] 33,30 mg

Glycyrrhiza glabra L. (Licorice) [root] 33,30 mg

Melissa officinalis L. (Lemon balm) [leaf] 33,30 mg

Silybum marianum (L.) Gaertn. (Milk thistle) [fruit] 33,30 mg

Mentha x piperita L. (Peppermint) [leaf] 16,70 mg

The other ingredients are: Ethyl alcohol (31 % v/v) and water.

What BIOGEN DIGESTIGAST looks like and contents of the pack

50 mL brown liquid in an amber glass bottle with a slow-flow dropper and a white cap.

Holder of certificate of registration

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This leaflet was last revised in

August 2022

Registration Number

Will be allocated by SAHPRA upon registration.

PASIËNTINLIGTINGSBLADSKEDULERINGSTATUS: PRODUKNAAM
BIOGEN DIGESTIGAST druppels

Angelica, Karwy, Ceylon kaneel, Duitse kamille, Gemmer, Suurleemoenbalsem, Drop, Melkdistel, Peperment.

Suikerury.

Bevat etielalkohol: 31 % v/v

Komplementêre medisyne: D 33.6 Westere Kruele Medisyne. Dissipline-Spesifieke Tradisionele Bewerings.

Gesondheidsoordingsvaluings dan slegs as aanvulling tot gesondheid of dieter.

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

Lees hierdie inligtingsbl