



Gastrointestinal adsorbent for use in Acute diarrhoea and Irritable bowel syndrome with diarrhoea

WHAT IS IN THIS LEAFLET

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

1. WHAT IS ENTEROSGEL® AND WHAT IT IS USED FOR

ENTEROSGEL® is an oral suspension indicated for the:

- Symptomatic treatment of acute diarrhoea.
- Treatment of Irritable bowel syndrome with diarrhoea (IBS-D).

ENTEROSGEL® is an oral intestinal adsorbent (enterosorbent) based on organic mineral with adsorption capacity towards some toxic and harmful substances in the gut (e.g. endotoxins, enterotoxins), physically binding them to its surface, reducing stool frequency and duration of diarrhoea.

ENTEROSGEL® is expelled from the body with the stool, this way eliminating the adsorbed toxins and harmful substances, which can be beneficial for treatment of indicated conditions.

ENTEROSGEL® relieves symptoms of diarrhoea, abdominal pain, bloating and urgency in IBS-D patients.

ENTEROSGEL® is free from preservatives, gluten, sugar, sweeteners, lactose, fat, flavours, colouring, plant or animal-derived ingredients.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ENTEROSGEL®

Do not use ENTEROSGEL® if (contraindications):

- you are currently taking modified-release orally administrated medications.
- you have intestinal atony or intestinal blockage (sever constipation due to bowel obstruction).
- you have intolerance based on prior use of ENTEROSGEL®

Precautions

- Do not use ENTEROSGEL® within 2 hours before or after taking oral medication. ENTEROSGEL® may affect the absorption of some medicines that are administered orally. If you are taking any medication, you may wish to consult with your doctor or pharmacist regarding taking ENTEROSGEL®.
- In case of long-term diarrhoea you should consult a doctor to obtain a diagnosis of the underlining condition before taking ENTEROSGEL®.
- In children, treatment of diarrhoea should be accompanied by plenty of fluids which may include an oral rehydration solution (ORS) to avoid dehydration.
- In adults, it is advisable to consume water or an ORS during the treatment with ENTEROSGEL® to assure proper hydration.
- Do not exceed the recommended duration of treatment and do not take together with meals to avoid possible adsorption of vitamins or nutrients.
- If diarrhoeal symptoms persist for more than 2 days you should consult your doctor.
- If there is fever, blood in your stools, signs of dehydration, six or more episodes of diarrhoea in the last 24 hours, diarrhoea and vomiting at the same time, or a severe or continuous stomach ache, seek medical advice especially in the case of children as soon as possible.
- Do not exceed the recommended dose and do not exceed the recommended duration of treatment
- Please, consult your doctor if you are currently taking other intestinal adsorbents, for example treatments which contain activated charcoal, clay, kaolin. Your doctor may advise not to use them together with ENTEROSGEL® treatment.
- ENTEROSGEL® is not indicated for use in case of acute chemical or drug poisoning or medicinal overdose.

- Do not use beyond the expiry date indicated on the package.

ENTEROSGEL® can be used during pregnancy and breastfeeding. It is advisable to consult with your healthcare professional if you are unwell during pregnancy or breastfeeding. Please, consult your doctor before taking ENTEROSGEL®.

3. HOW TO TAKE ENTEROSGEL®

- Take the necessary dose of ENTEROSGEL® after the first loose stool.
- Take ENTEROSGEL® at least 2 hours before or after taking oral medications.
- Take ENTEROSGEL® at least 1–2 hours before or after meal.
- Dilute the dose in the water of room temperature before its administration.
- Use sachet immediately after opening.
- Shake the tube well before opening and each use.
- Use a tube within 30 days after opening.



Age	Dosage	How often
Under 1 years	2.5g (≈ 1/2 teaspoon) diluted in 7.5–15ml of water.	3 times a day
1–6 years old	5g (≈ 1 teaspoon) diluted in 50–100ml of water.	3 times a day
7–14 years old	10g (≈ 2 teaspoons) diluted in 50–100ml of water.	3 times a day
15+ and adults	15g to 22.5g (≈ 1 tablespoon or 1–1.5 sachet) diluted in 200ml of water.	3 times a day



Duration of the treatment with ENTEROSGEL® is:

- 3–5 days for acute diarrhoea
- Up to 30 days for IBS-D. Break between repeated use should be at least 3 days.
- Prior to use in children under 3 years old it is advisable to consult a doctor.
- In the beginning of the treatment (on day 1) you can double the first dose and then continue with a single dose after each bowel movement. Maximum 8 doses on the first day.
- During treatment of chronic diarrhoea you may adjust your dosage to suit your stool consistency and bowel movements. You can increase treatment to a double dose up to 3 times a day if your stool is loose, or reduce to a single dose once a day if your stool is normal. Maximum 6 doses per day.
- Stop the treatment with ENTEROSGEL® if you do not have a bowel movement for 1–2 days, increase intake of water and continue the treatment after the next bowel movement.

4. POSSIBLE SIDE EFFECTS

Constipation, nausea

5. HOW TO STORE ENTEROSGEL®

- ENTEROSGEL® should not be used after the expiry date on the package.
- Keep out of reach of children.
- Store ENTEROSGEL® at temperature between 4 °C to 30 °C.
- Do not freeze.
- Keep away from direct sunlight and heat.
- The expiration date on the package refers to when the product is unopened and when properly stored.

For sachets

- Each sachet should be used only once after it is opened.
- Each sachet is disposable and should be opened immediately before use.
- Do not reuse partially used sachets to prevent microbial contamination.

For tubes

- Close the lid of the tube tightly after opening and after each use to avoid drying and to prevent microbial contamination.

When squeezing ENTEROSGEL® out of the tube or a sachet some amount of liquid may appear.

6. CONTENT OF THE PACK AND OTHER INFORMATION

Composition: Polymethylsiloxane polyhydrate (methylsilicic acid hydrogel) – 70%, purified water – 30%.

Package size

ENTEROSGEL® oral suspension
– Tube 225 g
– Tube 90 g
– Sachet 15 g (10 sachets per pack)

DISPOSAL

There are no special disposal requirements for unused ENTEROSGEL®. It can be safely disposed into the domestic waste. Packaging can be recycled.

Shelf life: Until date indicated on package

If you have any further questions about use of ENTEROSGEL® please email: info@enterosgel.eu.

This instructions for use leaflet (IFU) is also available in other languages at www.enterosgel.eu.

MANUFACTURER:



Bioline Products s.r.o.
Pátkova 831, Libeň,
182 00 Prague 8,
Czech Republic
www.enterosgel.eu

LAST DATE OF TEXT UPDATE:

08.08.2022

VERSION: TUV/IFU/EN/NB/3

EXPLANATION OF GRAPHIC SYMBOLS USED ON PACKAGE:



Do not re-use



Certified medical device



Minimum shelf life



Disposable packaging

LOT

Batch code



Dispose of used packaging in appropriate waste receptacle. Packaging can be recycled



Manufacturer



A fee for the national packaging management system has been paid for this packaging.



Please read the instructions



Keep away from direct sunlight



Temperature range
4°C to 30°C

CE 0123
Medical Device class IIa