INSTRUCTIONS FOR USE (IFU)

ENTEROSGEL®

Oral suspension

GASTROINTESTINAL ADSORBENT ENTEROSGEL® FOR USE IN ACUTE DIARRHOEA AND CHRONIC IBS DIARRHOEA.

ENTEROSGEL®

– Oral Suspension in tube 225 g
– Tube 90 g
– Sachet 15 g (10 sachets per pack)

INTENDED USE

ENTEROSGEL® is an oral suspension indicated for the symptomatic treatment of acute diarrhoea and chronic diarrhoea associated with Irritable Bowel Syndrome (IBS).

MECHANISM OF ACTION

ENTEROSGEL® is an oral intestinal adsorbent (enterosorbent). It is 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 of acute diarrhoea and chronic IBS diarrhoea.

Composition: polymethylsiloxane polyhydrate (methylsilicic acid hydrogel) – 70 %, purified water – 30 %. ENTEROSGEL® is free from preservatives, colouring, gluten, fat, sugar, lactose, flavours, plant or animal-derived ingredients.

INSTRUCTIONS FOR USE

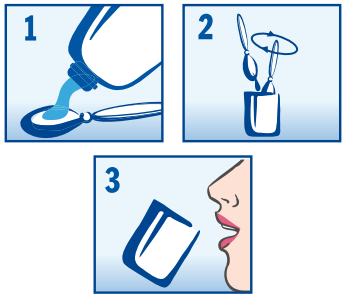
• Take ENTEROSGEL® treatment 2 hours before or after a meal and taking oral medications.

• Duration of treatment with ENTEROSGEL® is 3–5 days for acute diarrhoea and up to 21 days for chronic IBS diarrhoea diagnosed by a doctor.

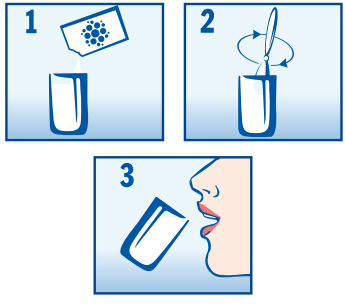
• Dilute the dose in water of room temperature prior to its administration.

• Use sachet immediately after opening. Dilute the content of a sachet in water.

ENTEROSGEL® IN A TUBE:



ENTEROSGEL® IN A SACHET:



DOSAGE:

Age	Dosage	How Often
Child 3–6 years old	5g (≈ 1 teaspoon)	3 times a day
	or 1/3 of sachet	
Child 7–14 years old	10g (≈ 2 teaspoons)	3 times a day
	or 2/3 of sachet	
15+ and adults	15 to 22.5g (≈1 tablespoon)	3 times a day
	1–1.5 sachet	

• Use a tube within 30 days after opening.

DURATION AND DOSAGE

• For children:

1–3 years old it is advisable to consult a doctor prior to use of ENTEROSGEL®.

1–6 years old: 5g (approximately 1 teaspoon or 1/3 of a sachet) diluted in 50–100 ml of water 3 times a day.

7–14 years old: 10g (approximately 2 teaspoons or 2/3 of a sachet) diluted in 50–100 ml of water 3 times a day.

• **For children 15+ and adults**

15 g to 22.5 g (approximately 1 table spoon or 1–1,5 sachet) diluted in 200 ml of water 3 times a day.

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 from 3 to 6 times a day. Maximum 8 doses on the first day.

• Stop the treatment with ENTEROSGEL® if you do not have bowel movement for 1–2 days, increase intake of water and continue the treatment after the next bowel movement.

• 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.

CONTRAINDICATIONS

Do not use ENTEROSGEL® if:

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

KNOWN SIDE EFFECTS

Constipation, nausea.

PREGNANCY AND BREASTFEEDING

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.

PRECAUTIONS

• ENTEROSGEL® may affect the absorption of some medicines that are administered orally – use ENTEROSGEL® **2 hours before or after taking oral medication**. If you are taking any medication, you may wish to consult with your doctor or pharmacist regarding taking ENTEROSGEL®.

• ENTEROSGEL® should be administered orally between meals.

• 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.

• 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.

• No clinical data is available on ENTEROSGEL® use in the first trimester of pregnancy. Please, consult your doctor before taking ENTEROSGEL®.

• Do not use after expiration date

• Do not use if package is damaged

• Keep out of the reach of children

• Do not exceed the recommended dose

• Do not exceed the recommended duration of treatment and do not take together with meal to avoid possible vitamin or nutrient deficiency.

• 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.

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

• Shake the tube well before opening and each use.

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

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

• Use tube within 30 days after opening.

Leaflet date of updated issue 21 November 2018.
Leaflet version 12/2018.
Latest safety and performance data: Study of adsorption capacity of ENTEROSGEL, 2017, UK; CER Bioline Products s.r.o., 2018

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STORAGE INSTRUCTIONS:

• 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 and 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.

DISPOSAL

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

Packaging: Oral suspension in tube 225 g, tube 90 g, sachet 15 g (10 sachets per package).

Shelf life: Three years. Not to be used beyond the expiry date indicated on the 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.

Explanation of graphic symbols on package:

Do not re-use

Minimum shelf life

Batch code

Manufacturer

Please read the instructions

Temperature range

Certified medical device

Disposable packaging.

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

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

Keep away from direct sunlight

ENTEROSGEL®

Medical device CE 0088

Manufacturer:
Bioline Products

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