

## Medical Device Patient Information Leaflet



Please read these medical device instructions carefully. Keep this leaflet as it contains important information that you should follow during use of this medical device. You may need to read it again. If you have any further questions, ask your doctor or pharmacist.

### 1. What is Enterosgel® and what is it used for?

Enterosgel® is a Class IIa medical device. Enterosgel® is an innovative intestinal adsorbent (enterosorbent) that binds toxins in the gastrointestinal tract and eliminates harmful substances, pathogens and allergens from the body.

Enterosgel is a suitable ancillary treatment for acute diarrhea.

#### Enterosgel® is used in children and adults for the following conditions:

- acute gastroenteritis (disease-associated diarrhea) in adults and children
- allergic diseases with gastrointestinal symptoms in adults and children
- irritable bowel syndrome with diarrhea (IBS-D)

#### Recommended dosage

Adults and children over 15: 15–22,5 g three times per day (15 g = 1 tablespoon)

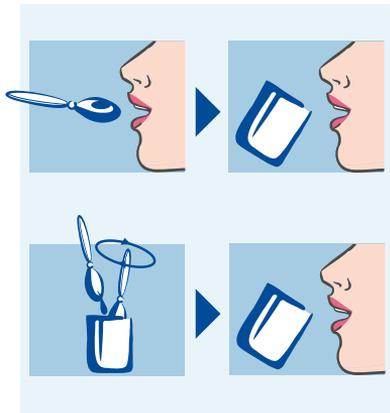
Children aged 7–14: 10 g three times per day (10 g = 2 teaspoons)

Children aged 1–6: 5 g three times per day (5 g = 1 teaspoon)

Wash down with a sufficient amount of fluid (200 ml for adults and children 7 and over, 50–100 ml for children aged 1–6).

A sufficient intake of fluids is also necessary as part of basic treatment of acute diarrhea.

Use 1–2 hours before or after meals or taking medication.



#### Note

Enterosgel® may affect the absorption of some medicines that are administered orally – use Enterosgel® 1–2 hours before or after taking medication.

If you are taking any medication, you may also consult with your doctor or pharmacist regarding taking Enterosgel®.

#### Contraindications

Intestinal atony, intestinal obstruction, intolerance based on prior use.

#### Pregnancy and breastfeeding

Enterosgel® may be taken during pregnancy or while breastfeeding.

#### Possible side effects

Nausea, vomiting, constipation.

### 2. Additional information

#### Composition:

polymethylsiloxane polyhydrate 70 %, purified water 30 %.

Enterosgel® is sugar-free, sweetener-free, lactose-free, gluten-free, fat-free, colour-free, flavour-free and preservative-free.

#### Packaging:

Oral suspension, tube 90 g, tube 225 g, sachet 15 g (10 sachets per pack).

#### Note:

Shake well before opening.

When squeezing Enterosgel® out of the tube some amount of liquid may appear.

#### Storage:

Store at temperatures of 4–25 °C. Do not freeze.

Keep out of reach of children.

Avoid drying out after opening the package.

Use this product within 30 days of opening the tube.

#### Shelf life:

3 years from the date of release. Best before: see on the package.

#### What to do if the package is damaged:

Do not use the product if the package is damaged.



#### Manufacturer:



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110 00 Prague 1, Czech Republic

tel./fax: + 420 266 317 783

e-mail: [info@enterosgel.eu](mailto:info@enterosgel.eu)

[www.enterosgel.eu](http://www.enterosgel.eu)

#### Distributor in Australia:

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[info@medsilica.com](mailto:info@medsilica.com)

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#### Distributor in New Zealand:

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## Explanation of graphic symbols on package:



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.

## Useful information on the mechanism of action of medical device Enterosgel®

### The gastrointestinal tract plays an essential role in maintaining good health:

- delivers necessary nutrients
- serves as one of the main routes of elimination of harmful substances and toxins
- performs barrier and immune functions

### Causes of diseases and symptoms of illness

Acute exposure of the gastrointestinal tract to pathogens, toxins, allergens and xenobiotics (pesticides, radionuclides, salts of heavy metals, etc.) results in the development of gastrointestinal infections, intoxication and allergic reactions. Harmful and toxic metabolites are produced during bodily function. Some of these reach the intestines, from which they are generally eliminated from the body with the faeces, but some harmful substances may be reabsorbed into the bloodstream again and transported back to the liver, remaining in the enterohepatic circulation. The most common symptoms of acute intoxication include a feeling of general malaise, headaches, nausea, vomiting, diarrhea, allergic manifestations and elevated body temperature. Long-term exposure to low concentrations of endogenous and exogenous toxins leads to chronic intoxication, which may be diagnosed as other diseases such as chronic fatigue syndrome or anaemia.

### Recommended measures = DETOXIFICATION

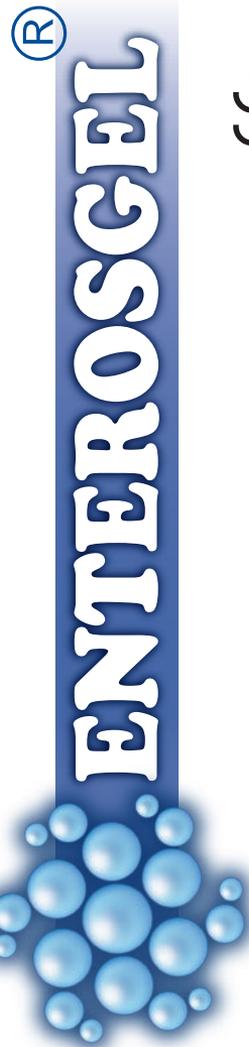
An important step on the path to recovery, optimal health and longevity is detoxification – removal of harmful substances, toxins and disease-causing microorganisms from the digestive tract.

Enterosgel® is a mineral-based gastrointestinal detoxifier. The device is not medicated. The device does not contain material or ingredients manufactured or formulated using a genetically modified organism. It is a patent of the Swiss company, Bioline Pharmaceutical. Enterosgel® is a Medical Device for the whole family, for use while travelling, camping, or on vacation.

Enterosgel® helps to eliminate harmful substances from the body.

Detoxification leads to improvement of general well-being, normalisation of digestion and augmentation of resistance to infection, and helps the body work under optimal conditions.

Enterosgel® is considered to be a medical device because it passes through the body unchanged. It is not absorbed and does not interact with normal bodily functions.



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