

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:

Until date indicated on package.

What to do if the package is damaged:

Do not use the product if the package is damaged.

Manufacturer:

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