

## PATIENT INFORMATION LEAFLET

### Enterosgel®

**Registration number:**

**Trade name:** Enterosgel®

**Generic name:** polymethylsiloxane polyhydrate.

**Chemical name:** product of non-linear polycondensation of 1,1,3,3-tetrahydroxy-1,3-dimethyldisiloxane polyhydrate.

**Pharmaceutical form:** paste for oral administration.

**Composition:**

100 g of the product contain:

*Active ingredient:*

Polymethylsiloxane polyhydrate	70 g
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*Excipient:*

Purified water	30 g
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**Description:** Homogeneous paste-like mass from white to almost white colour, odourless.

**Pharmacotherapeutic group:** intestinal adsorbent.

**ATC Code:** A07B.

**Pharmacological properties**

Enterosgel® has a porous structure of hydrophobic organic silicon matrix (molecular sponge) that sorbs mostly medium molecular toxic metabolites (m.m. 70 - 1000). The medicinal product has pronounced sorption and detoxification properties. In the intestinal lumen, it binds endogenous and exogenous toxic substances of various nature, including bacteria and bacterial toxins, antigens, food allergens, drugs and poisons, salts of heavy metals, radionuclides, alcohol and removes them from the body. Enterosgel® also sorbs some metabolic waste, including excess bilirubin, urea, cholesterol and lipid complexes, as well as metabolites responsible for endogenous toxicosis. Enterosgel® does not reduce absorption of vitamins and trace elements, it helps restore the damaged intestinal microflora. Enterosgel® does not affect gastrointestinal motor function.

**Pharmacokinetics**

Enterosgel® is not absorbed in the gastrointestinal tract, it is excreted unchanged in 12 hours.

**Therapeutic indications**

In adults and children as a detoxification agent:

- Acute and chronic intoxications of various causes;
- Acute intoxication by strong and poisonous substances, including drugs and alcohol, alkaloids, salts of heavy metals;
- Acute intestinal infections of any cause, as part of complex therapy (toxic infection, salmonellosis, dysentery, non-infectious diarrhoea, dysbacteriosis);
- Purulent-septic diseases aggravated by severe intoxication, as part of complex therapy;
- Food and drug allergies;
- Hyperbilirubinemia (viral hepatitis) and hyperazotemia (chronic renal failure);
- To prevent chronic intoxications in workers exposed to health and safety hazards (occupational intoxication by chemical agents of polytropic action, xenobiotics, incorporated radionuclides, lead compounds, mercury, arsenic, petroleum products, organic solvents, nitrogen oxides, carbon, fluorides, salts of heavy metals).

### **Contraindications**

Individual intolerance to the medicinal product, intestinal atony.

### **Use in pregnancy and lactation**

Enterosgel® is not contraindicated in pregnancy and lactation.

### **Dosage and method of administration**

Take Enterosgel® orally 1-2 hours before or 1-2 hours after a meal or intake of other medicines.

Take with water.

Stir the necessary amount of the medicinal product in a glass of water (ratio 1:3) at room temperature and drink the mixture, or take the medicinal product orally and wash it down with water.

Dosage for adults and children over 14 years: 15 g – 22.5 g (1 – 1.5 tablespoon) 3 times per day. Daily dose 45 g – 67.5 g.

Children aged 5 to 14 years – 15 g (1 tablespoon) 3 times per day.

Daily dose 45 g.

Children under 5 years – 7.5 g (0.5 tablespoon) 3 times per day.

Daily dose 22.5 g.

For children under 1 year mix 2.5 g (0.5 teaspoon) of the medicinal product with breast milk or water (ratio 1:3) and give before each feeding (6 times per day).

To prevent chronic intoxications - 22.5 g 2 times per day for 7-10 days monthly. In cases of severe intoxication, the dose of the medicinal product can be doubled during the first 3 days.

In cases of acute intoxication, the duration of treatment is 3-5 days. In cases of chronic intoxications and allergic conditions, the duration of treatment is 2-3 weeks. For repeat course, consult a doctor.

**Adverse reactions**

May cause nausea, constipation. In a condition of severe renal and/or liver failure, aversion towards the medicinal product may appear.

**Overdose**

No cases of overdose were reported.

**Interaction with other medicinal products**

Simultaneous intake of Enterosgel® with other medicines may reduce absorption of the latter.

**Special instructions and precautions for use**

Enterosgel® can be used in complex therapy with other medicines, provided a time interval of 1-2 hours is observed before or after intake of the latter.

**Effect on ability to drive and operate machinery**

Enterosgel® showed no effects on the ability to drive and operate machinery.

**Pharmaceutical form**

Paste for oral administration.

**Storage conditions**

Store at temperatures not below 4°C and not above 30°C. Keep out of the reach of children. Protect from drying after opening the package. Protect from freezing.

**Shelf life**

3 years. Do not use after the expiry date printed on the package.

**Dispensing conditions**

Over the counter.