

APPROVED
Order of the Ministry of
Health of Ukraine
July 25, 2017 No. 846
Marketing Authorization
No. UA/4415/03/01

AS AMENDED BY
Order of the Ministry of
Health of Ukraine

INSTRUCTIONS
for medical use

ENTEROSGEL EXTRACAPS (ENTEROSGELUM EXTRACAPS)

Composition:

active ingredient: polymethylsiloxane xerogel,
1 capsule contains polymethylsiloxane xerogel 0.32 g,
excipients: gelatin, titanium dioxide (E 171).

Pharmaceutical form. Oral capsules.

Main physicochemical properties: hard gelatin capsules, white body and cap. Capsules contain white or almost white odorless powder.

Pharmacotherapeutic group.

Enterosorbents. ATC code: A07B C.

Pharmacological properties.

Pharmacodynamic properties.

When taken orally, the medicinal product has a detoxifying effect. The medicinal product effectively adsorbs medium molecular toxic substances from the intestine and blood (through the capillary membranes of the villi of the intestinal mucosa), products of incomplete metabolism, promotes excretion of incorporated radionuclides. Enterosgel ExtraCaps eliminates the manifestations of toxicosis, improves the function of the intestines, liver, kidneys, normalizes blood and urine values. As an effective detoxifier, Enterosgel ExtraCaps boosts immunity.

Pharmacokinetic properties.

The medicinal product covers the mucous membrane of the stomach and intestines protecting it from erosive processes. The medicinal product is not absorbed from the intestinal tract.

Clinical particulars.

Therapeutic indications.

As a part of complex detoxification therapy in chronic renal failure caused by pyelonephritis, polycystic kidney disease, nephrolithiasis; in toxic hepatitis, viral hepatitis A and B, hepatocholecystitis, liver cirrhosis, cholestasis of various etiologies, gastritis with low acidity, enterocolitis, colitis, diarrhea; in alcohol and drug poisoning; in allergic reactions, skin diseases (diathesis, neurodermatitis); in burn toxicosis; purulent septic processes associated with intoxication; toxicosis during the first half of pregnancy; in the complex therapy of intestinal dysbiosis.

Contraindications.

Acute intestinal obstruction.

Individual intolerance to the ingredients of the medicinal product.

Interaction with other medicinal products and other forms of interaction.

Provided that the instructions for use are followed (Enterosgel ExtraCaps and other medicinal products should be taken separately), the medicinal product can be used in the complex therapy with other medicinal and prophylactic

/Seal: illegible/

products, including bacterial medicinal products (bifidobacteria, lactobacilli), herbal medicinal products, adaptogens, immunomodulators. Concomitant use with medicinal products that belong to the class of bile acid sequestrants, such as cholestyramine, is not recommended due to the increased likelihood of constipation.

The medicinal product should not be used with drugs containing silver.

Special warnings and precautions for use.

The medicinal product should be taken according to these instructions.

Pregnancy and lactation.

This medicinal product can be used during pregnancy or breastfeeding. Use in pregnant women prone to constipation should be limited.

Effects on ability to drive and use machines.

The medicinal product has no known effect on the ability to drive and use machines.

Posology and method of administration.

The medicinal product is intended for oral administration, 1–2 capsules 2–3 times a day 1.5–2 hours before or 2 hours after meals or other medications, with plenty of water.

For adults and children over 14 years of age, a single dose of the medicinal product is 1–2 capsules, daily dose – 6 capsules.

For children 6 to 14 years of age, a single dose is 1 capsule, daily dose – 3 capsules.

The course of treatment is 7 to 14 days.

In severe forms of diseases, the doubled single dose should be administered during the first three days, and in chronic conditions (chronic renal failure, liver cirrhosis), the course of treatment can be prolonged.

Paediatric population.

The medicinal product can be used in children over 6 years of age. To facilitate swallowing, the capsule (single dose) can be opened and mixed with a small amount of liquid before administration.

Overdose.

Exceeding the maximum single dose does not cause adverse reactions.

Undesirable effects.

Temporary constipation may develop during the first days of administration of the medicinal product. In order to prevent it, patients who are prone to constipation are recommended a cleansing enema or laxatives (lactulose, sodium picosulfate) at bedtime in the first two days of taking the medicinal product.

There may be manifestations of individual intolerance to the ingredients of the medicinal product.

Shelf life. 3 years.

Special precautions for storage.

Keep in original packaging at a temperature below 25°C out of the reach of children.

Nature and contents of container.

7 capsules in a blister. 1, 2, or 4 blisters in a cardboard box.

Legal category. Over-the-counter.

Manufacturer.

Ecologoprotective Firm KREOMA-PHARM PJSC.

Manufacturer's location and business address.

3 Radyshcheva St., Kyiv, 03680, Ukraine.

Applicant.

Ecologoprotective Firm KREOMA-PHARM PJSC.

Manufacturer's location and business address.

3 Radyshcheva St., Kyiv, 03680, Ukraine.

Date of revision of the text.

/Stamp: In accordance with the Registration Dossier/

/Stamp: In accordance with the Registration Dossier/

/Signature/

The text has been approved.

Date

/Seal: illegible/