APPROVED
Order of the Ministry of
Health of Ukraine
September 9, 2020 No. 2069
Marketing Authorization
No. UA/4415/01/01

AS AMENDED BY
Order of the Ministry of
Health of Ukraine
August 18, 2021 No. 1752

INSTRUCTIONS
for medical use

ENTEROSGEL WITH SWEET TASTE
(ENTEROSGELUM DULCIS)

Composition:
active ingredient: 100 g contains methyl-silicic acid hydrogel 69.9 g,
excipients: saccharin sodium dihydrate, sodium cyclamate, purified water.

Pharmaceutical form. Oral paste.
Main physicochemical properties: white, odorless homogeneous paste-like mass.

Pharmacotherapeutic group.
Enterosorbents. ATC code: A07B C.

Pharmacological properties.
Pharmacodynamic properties.
Enterosgel is an inert organosilicon compound. It has a sorption effect when used. The medicinal product effectively adsorbs medium molecular toxic substances of exogenous and endogenous origin, products of incomplete metabolism, incorporated radionuclides, and naturally excretes them from the body. Enterosgel eliminates the manifestations of toxicosis, improves intestinal function, detoxifying function of the liver, kidneys, normalizes blood and urine values.
Pharmacokinetic properties.
Covering the mucous membrane of the stomach and intestines, Enterosgel protects it from erosive processes, boosts local immunity. Enterosgel is not absorbed from the intestines and does not undergo metabolic or chemical transformations.

Clinical particulars.
Therapeutic indications.
Detoxification of the body in chronic renal failure caused by pyelonephritis, polycystic kidney disease, nephrolithiasis; in toxic hepatitis, viral hepatitis A and B, cholecystitis, 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 disease; purulent septic processes; toxicosis during the first half of pregnancy; as part of complex therapy of intestinal dysbiosis.

Contraindications.
Acute intestinal obstruction. Hypersensitivity to the ingredients of the medicinal product. Individual intolerance to the ingredients of the medicinal product.

Interaction with other medicinal products and other forms of interaction.
The medicinal product may reduce the effect of other concomitantly administered products. 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. Provided that the instructions for use are followed (Enterosgel and other medicinal products should be taken in 1.5–2 hour intervals), the medicinal product can be used in the complex therapy with other medicinal and prophylactic products, including prebiotics and probiotics (bifidobacteria, lactobacilli), herbal medicinal products, adaptogens, immunomodulators.

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, 2–3 times a day 1.5–2 hours before or 2 hours after meals or other medicinal products, with plenty of water.
For adults and children over 14 years of age, a single dose of the medicinal product is 15 g (one tablespoon), daily dose — 45 g.
For newborn children to 3 years of age, a single dose of the medicinal product is 5 g (one teaspoon), daily dose — 10 g; from 3 to 5 years of age — a single dose is 5 g, daily dose — 15 g; from 5 to 14 years of age — a single dose is 10 g (dessert spoon), daily dose — 30 g.
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 newborn children. In children under 2 years of age, a single dose of the medicinal product can be mixed with a small amount of water before use.

Overdose.
No cases of overdose have been reported. Overdose can intensify adverse effects.

Undesirable effects.
Dyspeptic phenomena may occur during the administration of the medicinal product. 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. Hypersensitivity reactions are possible. There may be manifestations of individual intolerance to the ingredients of the medicinal product.

Shelf life. 2 years.

Special precautions for storage.
Keep out of the reach of children. Keep in original packaging at a temperature below 25°C, avoid freezing. Once the package has been opened, keep under the same conditions in a tightly closed container.

Nature and contents of container.
135 g, 270 g, 405 g in a plastic container; 1 container in a cardboard box; 15 g in a sachet; 10 or 20 sachets in a cardboard box; 90 g or 225 g in a tube; 1 tube 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.

Date of revision of the text. August 18, 2021.