MINISTRY OF HEALTHCARE OF THE RUSSIAN FEDERATION

INSTRUCTIONS
for Medical Use of the medicinal product
Mezym® 20000

Read all of these instructions carefully before you start taking this medicine because it contains important information for you.
Save these instructions; you might need them again.
If you have any questions, consult your doctor.
The medication you taking has been prescribed to you personally, and it should not be transferred to other persons as it may cause them harm, even if they have the same symptoms as you.

Registration number:
Trade name: Mezym® 20000
International non-proprietary name or grouping name: Pancreatin
Pharmaceutical form: gastro-resistant film-coated tablets

Composition per one tablet:
Core:
Active substance: Pancreatin* – 220.00 - 293.34 mg with a minimum activity of the following:

lipase	20,000 U
amylase	12,000 U
protease	900 U

Excipients: lactose monohydrate, microcrystalline cellulose, colloidal silica, crospovidone (type A), magnesium stearate.
Coating: Hypromellose, methacrylic acid-ethyl acrylate copolymer (1:1), dispersion 30 % (dry mass), triethyl citrate, talc, titanium dioxide (E 171), simeticone emulsion 30 % (dry mass), macrogol 6000, carmellose sodium, polysorbate 80, vanilla flavour, bergamot flavour.
* produced from porcine pancreas

Description: Round biconvex coated tablets, from white to white with greyish tint, with a smooth surface, and specific odour, brown speckles may be visible along the score.

Pharmacotherapeutic group: Digestives, enzyme preparations

ATC code: A09AA02

Pharmacological properties

Pharmacodynamics. Pancreatin is porcine pancreas powder. The pancreatic enzymes that are part of pancreatin provide the proteolytic, amylolytic, and lipolytic activity and promote breakdown of proteins, fats and carbohydrates, improve the functional condition of gastrointestinal tract (GIT) and thereby normalising digestive processes.

Pharmacokinetics. Mezym® forte 20000 tablets are covered with a gastro-resistant coating which does not dissolve in gastric acid and thus protects the pancreatic enzymes contained against deactivation. The dissolution of gastro-resistant coating and release of enzymes occur at the neutral or slightly alkaline pH values.

Therapeutic indications

- Pancreas exocrine insufficiency (chronic pancreatitis, cystic fibrosis, etc.);
- Chronic inflammatory-dystrophic diseases of stomach, intestines, liver, gallbladder;
- Conditions after resection or irradiation of the GIT organs associated with the impairment of digestive processes, flatulence, diarrhoea (as a part of combined therapy);
- For improvement of digestion in patients with the normal function of the gastrointestinal tract in case of alimentation bias;
- Preparation for X-ray and ultrasonic investigations of organs of the abdominal cavity;
- Functional gastrointestinal disorders (intestinal infectious diseases, irritable bowel syndrome, etc.).

Contraindications

- Hypersensitivity to any component of the formulation;
- Acute pancreatitis and acute attacks of chronic pancreatitis during the florid phase of the disease. However, administration is acceptable in the phase of diminishing exacerbation during extension of the diet if signs of digestion problems are present.
- Hereditary galactose intolerance, lactase deficiency or glucose and galactose malabsorption syndrome;
- children under 3 years of age (for this pharmaceutical form).

Use during pregnancy and breast-feeding

Before using Mezym® 20000, if you are pregnant, think that you may be pregnant or plan a pregnancy, you should consult your doctor.

Before using Mezym® 20000 during breast-feeding, you should consult your doctor.
No data regarding use of pancreatin during pregnancy and breast-feeding is available.
During the pregnancy and the breast-feeding period, the administration of pancreatin is possible only in cases when the presumed benefit to the mother outweighs the potential risk to the foetus or child.

Posology and method of administration

The dosage of Mezym® 20000 is to be defined individually according to the type and severity of disease.
Unless otherwise prescribed, ***adults*** should take 1 - 2 tablets of Mezym® 20000 with meals. Preparation is administered orally, without breaking and chewing tablets (as the efficacy of Mezym® 20000 may be diminshed on chewing, and the enzymes contained may damage the mucous membrane of the mouth on release there) and having sufficient amount of water (e. g., a glass of water).
The daily dose corresponding to 15,000 - 20,000 lipase units per kg of a bodyweight should not be exceeded.
An increase in the dose should take place only under the supervision of a doctor and be focused on an improvement in the symptoms (e.g., resolving steatorrhoea and stomachache).
The duration of treatment is determined by the doctor and can vary anywhere from several days (in the case of digestion malfunction due to nutritional mishaps) to several months or even years (when continual substitution therapy is necessary).
The dose in ***children*** is to be determined by the doctor.

Dose for adults and children with cystic fibrosis

In patients with cystic fibrosis the dose should be determined depending on the severity of the disease symptoms, steatorrhea monitoring results, and maintaining an adequate nutritional status (see “Special instructions”).
The dose should not exceed 10,000 lipase units/kg body weight per day.
In **children**, the dosage regimen and the treatment duration are determined by the physician depending on the degree of severity of digestive disorders and the dietary composition calculated as of 1000 lipase units/kg of a child body weight per each meal for children under 4 years of age and 500 lipase units/kg per meal for those older than 4 years of age.
Consult your doctor if the complaints do not improve, they get worse, or if new symptoms appear after the treatment.

Use the preparation only in accordance with the indications, method of administration and dosage given in the Instructions.

Side effects

The possible side effects are listed below in the increasing order of frequency: very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (< 1/10,000), frequency not known (cannot be estimated from the available data).

Immune system disorders

Very rare: Allergic reactions of the immediate type (such as skin rash, urticaria, sneezing, lacrimation, bronchospasm, dyspnoea), gastrointestinal hypersensitivity.

Gastrointestinal disorders

Very rare: Diarrhoea, stomach discomfort, abdominal pain, nausea, formation of strictures in the ileocecal region and in the ascending colon in patients with cystic fibrosis following the administration of high doses of pancreatin.

Renal and urinary disorders

Frequency not known: Hyperuricosuria (see "Special instructions").

If you have any of the side effects indicated in the instructions or they get worse, or if you have noticed any other side effects not indicated in the instructions, tell your doctor.

Overdose

Symptoms: Hyperuricosuria and hyperuricaemia (especially in patients with cystic fibrosis taking high doses of enzyme preparations).

Treatment: Symptomatic treatment, discontinuation of the product.

Interaction with other medicinal products

The absorption of folic acid may be diminished by the intake of pancreatin products. The effect of hypoglycemic agents for oral administration (such as acarbose, miglitol) may decrease in simultaneous administration with digestive enzyme preparations containing carbohydrate-spliting enzymes (e.g. amylase).

If you are taking the mentioned or other drug products (including those obtained without a prescription), please talk to your doctor before using Mezym® 20000.

Special instructions

Administration of Mezym® 20000 is appropriate in acute pancreatitis and acute attacks of chronic pancreatitis (in the subsiding phase of the exacerbation), during dietary build-up if there is evidence of impairment to the pancreatic function remaining or persisting.
In patients with cystic fibrosis, especially when high doses of pancreatin are taken, hyperuricosuria may occur, therefore this group of patients should be monitored on concentration of uric acid in urine.
The formation of strictures in the ileocecal region and in the ascending colon in such patients has been reported.
Unusual abdominal discomfort or changes in the complaints should be examined as precaution, especially after administration of more than 10,000 lipase units/kg body weight per day.
Mezym® 20000 contains active enzymes that, on release in the oral cavity, for example through chewing, may lead to mucosal damage of the oral mucous membrane (which includes ulcerations). Therefore the tablets should be swallowed whole.
This medicinal product contains lactose, therefore it is contraindicated in patients with the rare hereditary galactose intolerance, lactase deficiency or glucose-galactose malabsorption.

Effects on ability to drive and use machines
Mezym® 20000 has no effect or has a negligible effect on the ability to drive and use machines.

Dosage form
Gastro-resistant, film-coated tablets, 20,000 units
10 gastro-resistant tablets in a blister [aluminium foil/aluminium foil].
1, 2 or 5 blisters along with the Instructions for Use in a cardboard box.

Storage conditions
Not above 30 °C.
Keep out of the sight and reach of children.

Shelf life
3 years.
Do not use after the expiration date indicated on the package.

Prescription status
Without a prescription.

Manufacturer

Berlin-Chemie AG

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Germany

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