INSTRUCTION
for medical use of the medicinal product

PANCREAZIM 10000

Composition:
active substance: pancreatin;
1 tablet contains pancreatin with an enzymatic activity not less than 10 000 Ph. Eur. U. of lipolytic activity, 7 500 Ph. Eur. U. of amylolytic activity, 400 Ph. Eur. U. of proteolytic activity;
excipients: sodium chloride, silica colloidal anhydrous, microcrystalline cellulose, crospovidone, sodium croscarmellose, povidone 25, magnesium stearate, methacrylate copolymer dispersion, talc, propylene glycol, titanium dioxide (E 171), carmoisine (E 122).

Pharmaceutical form. Gastro-resistant tablets.
Basic physical and chemical properties: Pink, round, biconvex, coated tablets with a slight characteristic odour. When viewed through a magnifying glass a core surrounded by a solid layer is visible upon fracture.

Pharmacotherapeutic group.
Alimentary tract and metabolism. Digestives, including enzymes. Multienzymes (lipase, protease etc.). ATC Code A09A A02.

Pharmacological properties.
Pharmacodynamics.
Multienzyme. Pancreatic enzymes (lipase, amylase and protease) in its composition facilitate digestion of fats, carbohydrates, proteins contributing to their complete absorption in the small intestine. In pancreatic diseases the drug compensates its exocrine insufficiency and helps to improve digestion.
Pharmacokinetics.
The coating of tablets is insoluble in gastric acid and protects the enzymes from their inactivation by gastric acid. Only under neutral or slightly alkaline medium of the small bowel the coating dissolves and release the enzymes.

Clinical characteristics.
Indications.
Diseases associated with impaired digestion due to deficient exocrine pancreatic secretion, such as chronic pancreatitis.
Conditions after simultaneous resection of the stomach and small intestine, functional accelerated passage of food through the intestines, bowel disorders, simultaneous use of hard-to-digest vegetable, fatty and unusual foods.
Flatulence and preparation for X-ray or ultrasound diagnostic tests.

Contraindications.
Hypersensitivity to the active substance or to any of the drug components. Acute pancreatitis, chronic pancreatitis in its acute stage, obstructing adhesion.

Interaction with other medicinal products and other forms of interaction.
The medicinal product decreases iron absorption when prolonged administration, that's why in case of necessity it is necessary to administer iron-containing medicinal products simultaneously. Concomitant administration of antacid drugs containing calcium carbonate and/or magnesium hydroxide can lead to decrease of pancreatin efficacy.
Concomitant administration with tannin, alcohol-containing drugs can lead to decrease of pancreatin efficacy.
Pancreas enzymes inhibit absorption of folic acid. When concomitant administration of bicarbonates and cimetidine with high doses of pancreas enzymes it is recommended to perform periodically

analysis of folic acid salts concentration in blood serum and to ensure additional administration of folic acid if necessary.
Pancreas enzymes may decrease efficacy of acarbose and miglitol.

Special warnings and precautions for use.
When patient experiences symptoms similar to intestinal obstruction, the possibility of intestinal strictures should be considered. Monitoring of all unusual symptoms, especially when administration of more than 10 000 Ph. Eur. U. lipase/kg/day, is recommended.
The drug contains active enzymes that can damage the mucosa of the oral cavity, therefore the tablets should be swallowed intact without chewing.

Use during pregnancy and in nursing women.
There are no data on lipase, amylase and protease safety during pregnancy.
During studies in animals no direct or indirect negative impact on pregnancy, embryofetal development, childbirth or postnatal development was reported.
The medicinal product has to be administered in pregnant women with caution. Enzymes are not absorbed by gastro-intestinal tract, however the risk cannot be excluded. During pregnancy and lactation the drug should be taken only on prescription if the expected benefit to the mother outweighs the potential risk to the foetus/baby.

Effects on ability to drive and use machines.
The effects on ability to drive and use dangerous machines were not stated.

Dosage and administration.
Dosage is individual according to pancreatic enzyme deficiency in the duodenum.
Unless there are no other recommendations and in cases with hard-to-digest vegetable, fatty or unusual foods, 1-2 tablets should be taken. In other above-mentioned cases of indigestion the recommended dose is 2-4 tablets. If necessary, the dose can be increased. To reduce the symptoms such as steatorrhea or abdominal pain the dose should be increased only under medical supervision. The daily dose should not exceed 15 000-20 000 Ph. Eur. U of lipase per 1 kg of body weight.
The tablets should be taken with food, swallowed whole with a large amount of liquid, for example, 1 glass of water.
The duration of treatment depends on the course of disease and is determined by a physician individually.
Dosage and therapy duration in children are determined by a physician.
The medicinal product should be indicated in daily dose which is necessary to normalize evacuation but not more than 1 500 Ph. Eur. U. of lipase for 1 kg of bodyweight a child aged under 12 years. For children aged over 12 years daily dose of enzymes should not be more than 15 000 – 20 000 Ph. Eur. U. lipase for 1 kg of bodyweight.

Children.
It can be administered in children aged over 3 years.

Overdose.
Symptoms. Adverse reactions aggravation is possible. Extremely high doses of pancreatin have been reported to be associated with hyperuricosuria and hyperuricaemia, in children – constipation.
Therapy. Suspending medicinal product intake, sufficient hydration and symptomatic therapy.

Undesirable effects.
To estimate the incidence of adverse effects the following classification is used: very common: ≥ 1/10; common: ≥ 1/100 and < 1/10; uncommon ≥ 1/1000 and < 1/100; rare: ≥ 1/10000 and < 1/1000; very rare: < 1/10000, rate is unknown (assessment impossible based on available data).
Cardiac and vascular disorders: rate is unknown: tachycardia.
Immune system disorders: very rare: immediate type allergic reactions (skin rash, pruritus, sneezing,

epiphora, bronchial spasm), anaphylactic reactions. Rate is unknown: colourant carmoisine (E 122) can cause allergic reactions.
Gastrointestinal disorders: very rare: receiving high doses of pancreatin (more than 10 000 Ph. Eur. U. of lipase/kg of bodyweight/day) can develop strictures in the ileo-caecum and ascending colon; diarrhea, abdominal pain, nausea, vomiting, abnormal stool; intestinal obstruction, constipation may develop.
Skin and subcutaneous tissues disorders: rate is unknown: urticaria, hyperemia, pruritus, angioedema.
Renal and urinary tract disorders: rate is unknown: increased excretion of uric acid in the urine, especially with high doses of pancreatin, is possible. To avoid the formation of uric acid stones in such patients its concentration in the urine should be monitored.
General disorders: rate is unknown: fever sensation, general weakness.

Shelf life. 2 years.

Storage.
Store in the original packaging below 30 ^{0}C. Keep away from children.

Package.
10 tablets in a blister; 2 or 5 blisters in a cardboard pack.

Prescription status.
OTC.

Group of Pharmaceutical Companies «Lekhim»
Manufacturer: PJSC «Technolog»
Site address: Building 8, Stara Prorizna Street, Uman City
Cherkasy region, 20300, Ukraine.