MINISTRY OF PUBLIC HEALTHCARE OF THE RUSSIAN FEDERATION

INSTRUCTION
for medical use of
Mezym® forte 10000

Marketing License Number:
Trade Patented Name: Mezym® forte 10000
International Non-Patented Name or Group Name: Pancreatin
Pharmaceutical form: Tablets with enteric coating.

Composition as per one tablet
Core
Active Substance: Pancreatin powder-137,500 mg with the minimal fermentative activity of
lipase 10000 IU Ph.Eur.
amylase 7500 IU Ph.Eur.
protease 375 IU Ph.Eur.
Excipients: Lactose Monohydrate – 89,100 mg, Microcrystalline Cellulose – 52,000 mg, Silicium dioxide colloid – 1,533 mg, Crospovidone- 18,000 mg, Magnesium Stearate – 1,867 mg;
Coating: Hypromellose (~5 mPa· s) – 4,800 mg, Methacrylic acid etacrylate copolymer (1:1) dispersion 30 % (dry mass) – 12,200 mg, Triethylcitrate – 3,900 mg, Titanium dioxide (E 171) – 5,050 mg, Talc – 6,780 mg, Emulsion of simethicon 30% (dry mass) – 0,049 mg, Macrogol 6000 – 0,210 mg, Sodium Carmellose (~ 30 mPa·s) – 0,440 mg, Polysorbate 80 – 0,690 mg, Azorubine Laquer (E 122) – 0,232 mg, Sodium Hydroxide – 0,035 mg.

Description: Pink plano-cylinder tablets, film-coated, biconvex, with beveled edges, the fracture possibly shows brown inclusions.

Pharmacotherapeutic group: digestive enzyme agent
ATC Code: A09AA02 .

Pharmacological properties
Pharmacodynamics. Enzyme digestion-improving preparation.
Pancreatin is a powder made of porcine pancreas, containing other enzymes along with the exocrine pancreatic ferments – lipase, amylase, protease, trypsin and chymotrypsin.
The pancreatic ferments within the drug facilitate proteolysis, lipolysis and breaking of carbohydrates resulting in their improved absorption within the small intestines. Trypsin suppresses the induced pancreas secretion, rendering some analgesic effect. The highest

enzymatic activity of the drug becomes perceptible in 30-45 minutes after the oral administration of the drug.

Pharmacokinetics. The Mezym® forte 10000 tablets are covered by an acid-resistant coating not dissolved by the hydrochloric acid in the stomach thereby protecting the enzymes in the drug from inactivation. Dissolution of the coating and release of the enzymes takes place at the pH value close to the neutral pH or slightly alkaline pH.

Indications for use

- Replacement therapy in the insufficient exocrine secretion of pancreas (chronic pancreatitis, cystic fibrosis and so forth);
- Chronic inflammatory and dystrophic diseases of stomach, intestine, liver, gallbladder;
- States following resection or irradiation treatment of the said organs accompanied by digestive disorders, meteorism, diarrhea (as part of the complex therapy);
- Functional disorders of the gastrointestinal tract (gastrointestinal infections, irritable bowel syndrome);
- For improvement of digestion in patients with normally functioning gastrointestinal tract in case of overeating and diet excesses.
- Preparation for radiological and ultrasonic examination of organs in the abdominal cavity.

Contraindications

- Acute pancreatitis;
- Acute stage of chronic pancreatitis;
- Hypersensitivity to pancreatin or to other components of the drug;
- Hereditary idiosyncrasy to galactose, lactase deficit of the glucose/galactose malabsorption syndrome;
- In children younger than 3 years (non-divisible pharmaceutical form).

Pregnancy and lactation

As there is no sufficient information concerning the use of the pancreatic enzymes in humans during pregnancy and lactation, administration of Mezym® forte 10000 in pregnant or lactating patients is possible only when the expected benefit to mother exceeds the possible risks to fetus or to baby.

Posology and Administration

The dose Mezym® forte 10000 is adjusted individually depending on the severity of the gastrointestinal disorders and the composition of the patient's diet.
If not otherwise prescribed the average single dose for ***adults*** is 2 – 4 tablets of Mezym® forte 10000 per meal. It is recommended to take one half or one third of the dose at the beginning of the meal, and take the rest during the meal. The tablets are swallowed without chewing and washed down with sufficient amount of liquid.

Dose may be increased only by the attending physician, under the control of the symptoms (for example, steatorrhea, stomach pains). The maximum daily dose is 15000-20000 IU Ph. Eur. lipase/1 kg body mass.
In children the dose regimen should be prescribed by the attending physician depending on the severity of the disease and on the diet, calculated as 500-1000 IU Ph. Eur. lipase/ 1 kg body mass of the child per each meal.
Duration of treatment may vary from a few days treatment (when there are digestive disorders due to food abuse) to several months or years (when continuous replacement treatment is required).

Side Effects
There have been no side effects or complications reported even in prolonged and regular administration of Mezym® forte 10000 to patients with the pancreatic function disorders.
In individual cases, the allergic reactions may develop following the administration of the drug; rarely – diarrhea or constipation, nausea, feeling of discomfort in epigastrium.
In very rare cases, patients with cystic fibrosis may develop hyperuricosuria (increase of uric acid in the blood plasma) long-term use of high doses of the drug. In cystic fibrosis, there may be strictures developed in the ileocecal department and in the ascending colon.

Overdosage
There have been no reports concerning the overdosage or intoxication with the drug.
Possible events: hyperuricosuria, hyperuricemia, constipation in children.
Treatment: discontinuance of the drug, symptomatic treatment.

Interaction with other pharmaceutical drugs
When the pancreatin-containing drugs are taken the absorption of the folic acid may diminish. The sugar-reducing drugs (acarbose, miglitol) may be weakened if they are taken concomitantly with pancreatin.
If pancreatin is administered simultaneously with the preparations of iron, the absorption of the latter may be inhibited. Concomitant administration of the antacide agents containing calcium carbonate and/or magnesium hydroxide may result in the weakened effect of pancreatin.

Special warnings and precautions
In acute pancreatitis or in acute stage of the chronic pancreatitis (recovery from the acute stage), during the recovery diet regimen, Mezym® forte 10000 should be administered against the background of the existing or remaining insufficiency of the pancreas function.
Mezym® forte 10000, as it is manufactured as a solid non-divisible pharmaceutical form, is contraindicated to children younger than 3 years of age.

Effect of the drug on the driving abilities and skills and work with machines and mechanisms
Mezym® forte 10000 does not affect the speed of the psychomotoric reactions or the perception of assessment of any situation.

Dosage form
Tablets coated with an enteric coating
10 tablets in the blister packs made of aluminum foil /PVC/polyamide.
1 or 2 blisters together with the patient information leaflet in a folding cardboard box.

Storage condition
At temperature not exceeding 25°C.
Keep out of the reach of children!

Shelf life
3 years.
Do not use after the date of expiry.

Release from the Drugstores
Over the counter drug.

Manufacturer
Berlin- Chemie AG
Tempelhofer Weg 83
12347, Berlin
Germany

or

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