

**Translation from Russian into English
The text of translation**

INSTRUCTION

on the medical usage of drug preparation

Mezym[®] forte

Registration number:

Trade proprietary name of preparation: Mezym[®] forte

International non-proprietary name or grouping name: Pancreatine

Dosage form: film-coated tablets

Composition:

1 film-coated tablet contains:

Core:

Pancreatine with a minimal activity of:

lipase 3 500 U (Eur. Ph.)

amylase 4 200 U (Eur. Ph.)

general protease 250 U (Eur. Ph.)

List of excipients:

Microcrystalline cellulose - 98,140 mg; carboxymethyl starch sodium salt (type A) – 12,500 mg;
Colloidal silica dioxide - 4,000 mg; Magnesium stearate - 0,750 mg.

Coating:

Talc – 2,243 mg; Hypromellose - 2,243 mg; azo ruby varnish (E 122) – 0,076 mg; Simethicone emulsion 30 % (dry mass) – 0,005 mg; polyacrylate 30 % dispersion (dry mass) – 1,495 mg; Titanium dioxide (E 171) – 2,243 mg; Macrogol 6000 - 0,872 mg.

Description: pink plano-cylinder film-coated tablets, with almost parallel-plate surfaces and sloped edges, having specific odor of pancreatine.

Pharmacotherapeutic group: digestive enzymatic agent.

ATC code: A09AA02.

Pharmacological properties:

Drug preparation compensates the insufficiency of exocrinous function of the pancreatic gland. The pancreatic enzymes lipase, amylase and protease, which are components of Pancreatine, improve splitting of fats, carbohydrates and proteins, which promotes their more complete absorption in the small intestines.

Indications for Usage:

- Pancreas exocrine insufficiency, (chronic pancreatitis, mucoviscidosis, etc.);
- Chronic inflammatory-dystrophic diseases of stomach, intestines, liver, gallbladder.
- Conditions after resection or irradiation of these organs associated with the impairment of digestive processes, flatulence, diarrhea (as a part of the combined therapy).
- For improvement of digestion in patients with the normal function of the gastrointestinal tract in case of alimentation bias.
- Preparation for roentgenological and ultrasonic investigations of organs of the abdominal cavity.

Contraindications:

Hypersensitivity to ingredients of the drug preparation, acute pancreatitis, exacerbation of chronic pancreatitis.

Posology and mode of administration:

The dose of the drug preparation should be individually chosen depending on the type and severity of digestive disorder.

Adults: 1 – 2 tablets before meals without chewing and having water.

If necessary, 1 – 4 tablets are additionally taken with meals.

Children: the drug preparation is prescribed by the physician.

The treatment duration may vary from some days (in case of violations of digestive process due to the alimentary bias) to several months and years (if the permanent replacement therapy is necessary).

Side effects:

Allergic reactions, diarrhea or constipation, nausea, discomfort in the epigastria area. In long lasting therapy at high dosages, the development of hyperuricozuria, increase in plasma levels of uric acid is possible.

There are spontaneous reports in patients with mucoviscidosis, that the development of strictures in ileocecal part is observed after high dosages are administered.

Administration during pregnancy:

The safety of Pancreatine administration during pregnancy is not sufficiently studied. The administration is possible in cases where the expected benefits for mother overweigh the potential risks for fetus.

Drug interactions / Interaction with other medical products:

In simultaneous administration of Pancreatine with ferric preparations, the decrease of their absorption is possible. Simultaneous administration of Pancreatine with antacid agents containing calcium carbonate and/or magnesium hydroxide may cause the decrease of Pancreatine efficacy.

Pack presentation:

Film-coated tablets.

20 tablets per a contour bubble packaging (blister) of PVC/aluminum foil or PVC/PE/PVDC/aluminium foil.

1, 2, 4 or 5 blisters along with the instruction on medical use per a carton box.

Storage conditions:

Keep at temperature below 25 °C.

Keep the drug preparation out of the reach of children!

Shelf-life:

3 years.

Do not use after the expiration of the shelf life.

Terms of discharge (OTC-status):

Over-the-counter drug.

Manufacturing company:

Berlin - Chemie AG

Tempelhofer Weg, 83

12347, Berlin, Germany

While packaging at ZAO «Berlin-Pharma»:

Packed at:

ZAO «Berlin-Pharma»
Russia, 248926, Kaluga city,
2nd Avtomobilny Proezd, 5.

Address for raising claims:

123317, Moscow, Presnenskaya quay, 10, BC “Tower on Quay”, Block B.
Phone: (495) 785-01-00, Fax: (495) 785-01-01.

To whom it may concern

GUARANTEE OF TRANSLATION QUALITY

Dear Sir/Madam,

I hereby confirm that the invoiced translation: “Утвержденная инструкция + Изменение № 1 + Изменение № 2”

From: Russian / English

is correct and complete from a content and linguistic point of view. The quality of the translation is guaranteed.

Yours faithfully,

(signature)

Ludmila Kshevinskaya