

Package leaflet: Information for the user

MEZYM 10000, gastro-resistant tablets

Digestive enzymes of the pancreas

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What MEZYM 10000 is and what it is used for
2. What you need to know before you use MEZYM 10000
3. How to take MEZYM 10000
4. Possible side effects
5. How to store MEZYM 10000
6. Contents of the pack and other information

1. What MEZYM 10000 is and what it is used for

Mezym 10000 contains digestive enzymes of the pancreas (pancreatic enzymes).

Mezym 10000 is indicated for insufficient formation and release of digestive enzymes in the pancreas with concomitant digestive disorders (enzyme replacement therapy).

Cystic fibrosis (mucoviscidosis), if pancreatic function is insufficient.

2. What you need to know before you use MEZYM 10000

Do not take MEZYM 10000:

- If you are allergic to pig pancreatin, pig protein, colouring agent E122 (azorubine) or any of the other ingredients of this medicine (listed in section 6);
- If you have acute inflammation of pancreas (pancreatitis) and in the acute phase of chronic pancreatitis.

Warnings and precautions

Talk to your doctor or pharmacist before taking Mezym 10000.

Do not chew Mezym 10000 tablets, swallow them whole. Mezym 10000 contains enzymes that may damage the mucous membranes of the mouth (ulceration).

Patients with cystic fibrosis have been observed to experience the formation of strictures in the ileocecal region (fibrosing colonopathy) after receiving high doses of pancreatin. This should be considered in the course of treatment when assessing the complaints similar to constipation.

Other medicines and MEZYM 10000

Tell your doctor or pharmacist if you are using or have recently used any other medicines.

The absorption of folic acid may be reduced when using Mezym 10000, meaning that additional folic acid administration may be required.

The effect of medicines for controlling blood sugar levels (oral antidiabetics like acarbose and miglitol) may be reduced due to simultaneous administration of Mezym 10000.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

There are no data from the use of this medicine in pregnant or breast-feeding women. The potential risk for humans is unknown and thus Mezym 10000 must not be used during pregnancy and breast-feeding unless your doctor tells you to.

Driving and using machines

No special precautions are required because Mezym 10000 has no effect on the ability to drive or use machines.

Mezym 10000 contains lactose

This medicine contains lactose. If you have been told by your doctor that you have intolerance to some sugars, consult your doctor before taking this medicine.

3. How to take MEZYM 10000

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The dosage of Mezym 10000 depends on the severity of digestive disorders. As a rule, the proper dose is determined individually.

The recommended dose is 2...4 gastro-resistant tablets, administered during the meal.

Necessary dose can be increased depending on food and severity of digestive disorder. The dose can be increased only under the supervision of a doctor and it depends on the improvement in symptoms (such as steatorrhea and abdominal pain).

Do not exceed maximum daily dose 15 000...20 000 units of lipase per kilogram of body weight.

In particular for patients with cystic fibrosis, the dose should be set in consideration of the quantity and composition of food while not exceeding the quantity of enzymes usually required for digestion of fats.

The need for extended use of the medicine is decided by the doctor.

Use in children and adolescents

Dose and duration of treatment suitable for children and adolescents is determined by a doctor.

Method of administration

Gastro-resistant tablets are swallowed whole, washed down with adequate quantity of liquid.

If you take more MEZYM 10000 than you should

No harmful effects have been described for overdose.

If you forget to take MEZYM 10000

Do not take a double dose to make up for a forgotten dose.

If you stop taking MEZYM 10000

If you stop treatment with Mezym 10000 early or discontinue treatment, you might not achieve the desired therapeutic effect and your "poor digestion" may worsen again.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following frequency data are used in the evaluation of side effects.

If you develop any of the side effects described below, stop taking Mezym 10000 and contact your doctor as soon as possible.

Very rare: may affect up to 1 in 10 000 people

Gastrointestinal side effects:

Formation of strictures in the ileocecal region (fibrosing colonopathy) after receiving high doses of pancreatin (active substance of Mezym 10000) has been observed in patients with cystic fibrosis.

There have been reports of hypersensitivity reactions, manifested as gastrointestinal disorders (such as diarrhoea, upset stomach and nausea).

Immune system disorders:

Hypersensitivity reactions (rash, sneezing, tearing, shortness of breath resulting from bronchospasm).

Not known: cannot be estimated from the available data

Renal and urinary disorders

There have been reports of increased urinary excretion of uric acid in patients with cystic fibrosis, especially when using very high doses of medicine.

Uric acid content in the urine must be checked to avoid potential stone formation.

Colouring agent E122 (azorubine) may cause allergic reactions.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via www.ravimiamet.ee. By reporting side effects, you can help provide more information on the safety of this medicine.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store MEZYM 10000

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not store above 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Mezym 10000 contains

One gastro-resistant tablet contains 80.00 – 111.11 mg of pig pancreatic powder, equal to the following minimum activity:

Lipase activity	10 000 Ph. Eur. units per tablet
Minimal amylase activity	7500 Ph. Eur. units per tablet
Minimal protease activity	375 Ph. Eur. units per tablet.

Pancreas powder has been made of pancreatic tissue of pigs.

The other ingredients are lactose monohydrate, microcrystalline cellulose, colloidal anhydrous silica, crospovidone, magnesium stearate, hypromellose, methacrylic acid and ethyl acrylate copolymer, triethyl citrate, talk, 30% simethicone emulsion, macrogol 6000, carmellose sodium, polysorbate 80, colouring agents E 171 (titanium dioxide) and E 122 (azorubine), sodium hydroxide.

What MEZYM 10000 looks like and contents of the pack

Pink, almost biplane, film-coated tablets with bevelled edges (tablet height approximately 4 mm). Original pack contains 10, 20, 50 or 100 tablets.

Marketing Authorisation Holder and Manufacturer

BERLIN-CHEMIE AG (MENARINI GROUP)

Glienicker Weg 125

12489 Berlin

Germany

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

OÜ Berlin-Chemie Menarini Eesti

Paldiski mnt 27/29

Tallinn 10612

This leaflet was last revised in May 2015.