

Package leaflet: Information for the user

Panzynorm 10 000, gastro-resistant capsule, hard

Lipase, amylase, protease

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

Always use 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

What is in this leaflet

1. What Panzynorm 10 000 is and what it is used for
2. What you need to know before you use Panzynorm 10 000
3. How to take Panzynorm 10 000
4. Possible side effects
5. How to store Panzynorm 10 000
6. Contents of the pack and other information

1. What Panzynorm 10 000 is and what it is used for

Panzynorm 10 000 contains naturally occurring enzymes produced in pancreas: lipase, amylase and protease. These substances are usually released to the small intestine when we eat and they help to break down and digest different food components. Lipase ensures digestion of dietary fats, amylase breaks down carbohydrates and protease breaks down proteins. The ingredients of Panzynorm 10 000 originate from pigs and are extremely similar to the substances present in human body.

Panzynorm 10 000 is used for treatment of indigestion resulting from the deficiency of digestive enzymes due to impaired pancreatic function (with symptoms such as liquid, fatty, smelly bulky faeces, diarrhoea, flatulence, weight loss).

2. What you need to know before you use Panzynorm 10 000

Do not take Panzynorm 10 000:

- if you are allergic to active substance(s) or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Panzynorm 10 000.

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.

Tell your doctor if you have cystic fibrosis and you are taking 10 000 units of lipase per kg body weight daily and you have unusual abdominal complaints or changes in such complaints.

Panzynorm 10 000 with food and drink

Take the capsule at mealtime with fluid.

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.

Driving and using machines

Panzynorm 10 000 has no or negligible influence on the ability to drive or use machines.

3. How to take Panzynorm 10 000

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 depends on the severity of disease. The usual dose is 1 to 2 capsules during main meals, but you may also take 1 capsule during other meals if necessary. The dose is sufficient if it ensures normal bowel movement and normal body weight. Increased dose is required by patients with full pancreatic insufficiency and such doses must be prescribed by a doctor. It is important to use the lowest effective dose.

Capsules must be swallowed whole, without chewing them.

Use in children and adolescents

Starting dose for children under 4 years and over 4 years of age is 1,000 units of lipase/kg body weight/meal and 500 units of lipase/kg body weight/meal, respectively. The dosage must be adjusted according to the severity of disease, the amount of undigested dietary fat in faeces (steatorrhea) and the maintenance of good nutritional status. Daily dose should not exceed 10,000 units of lipase/kg body weight.

If the child cannot swallow entire capsule, you may open the capsule and stir its contents with a little water or fruit juice. Administer the mixture to the child immediately, do not crush or chew.

If you feel that the effect of Panzynorm 10 000 is too strong or too weak, talk to your doctor or pharmacist.

If you take more Panzynorm 10 000 than you should

If you have taken too high a dose of Panzynorm 10 000, drink plenty of water and consult with your doctor or pharmacist immediately.

Increased level of uric acid in urine (hyperuricosuria) and in the blood (hyperuricemia) has been observed after receiving very high doses of pancreatin.

If you forget to take Panzynorm 10 000

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

If you forget to take this medicine, take the next dose with your next meal.

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.

Very common (may affect more than 1 in 10 people):

- abdominal pain.

Common (may affect up to 1 in 10 people):

- feeling unwell or feelings of illness,
- constipation,
- flatulence,
- diarrhoea.

Rare (may affect up to 1 in 1,000 people):

- skin reactions, rash.

Not known (cannot be estimated from the available data).

- allergic reactions (which can be serious),
- severe or prolonged abdominal pain (fibrosing colonopathy),
- itching, with or without rash.

Increased levels of uric acid in the blood and urine have been observed in some patients after receiving very high doses.

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.

5. How to store Panzynorm 10 000

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 package. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original package, protected from humidity.

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 Panzynorm 10 000 contains

The active substances are lipase, amylase, protease

- One gastro-resistant hard capsule contains 10,000 units of lipase, 7,200 units of amylase and 400 units of protease.
- The excipients are methacrylic acid and ethyl acrylate copolymer (1:1), tri-ethyl citrate, talc (E553b) and simethicone, all in the capsule core, and gelatine (E441) and titanium dioxide (E171), all in the capsule coating.

What Panzynorm 10 000 looks like and contents of the pack

Panzynorm 10 000 gastro-resistant hard capsules have white opaque cap and body, filled with brown granules. Length of the capsule: 15.6-16.2 mm.

OPA/Al/PVC-Al blister pack with 21, 56 or 84 gastro-resistant hard capsules in a carton.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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

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