Package leaflet: Information for the patient

Norzyme 25,000 gastro-resistant capsules, hard

Pancreas powder (pancreatic extract)

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 prescribed by your doctor or dietician.

- 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 5 days.
- This medicine has been prescribed for you personally. Don't offer it to other people, even if their symptoms seem to be the same as yours.

What is in this leaflet

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2. What you need to know before you take Norzyme
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1. What Norzyme is and what it is used for

What Norzyme is

- Norzyme is a pancreatic enzyme supplement.
- Pancreatic enzyme supplements are used for the treatment of pancreatic exocrine insufficiency. This is when the pancreas gland does not produce enough enzymes to digest food.
- Norzyme contains an enzyme mixture called pancreas powder.
- Pancreas powder is also called pancreatic extract. It helps to digest food. The enzymes are taken from pig pancreas glands.
- Norzyme contains gastro-resistant micropellets of small size which slowly release the pancreas powder in the gut.

How Norzyme works

The enzymes in Norzyme work by digesting food as it passes through the gut. Therefore, you must take Norzyme during or immediately after a meal or a snack. This will allow the enzymes to mix thoroughly with the food.

2. What you need to know before you take Norzyme

Do not take Norzyme

if you are allergic to pork, any pig product or to any of the other ingredients of this medicine listed in section 6.

If the above applies to you, do not take Norzyme. Talk to your doctor or dietician again.

When you need to take special care with Norzyme

A rare bowel condition called “fibrosing colonopathy”, where your gut is narrowed, has been reported in patients with cystic fibrosis taking high dose of products containing pancreas powder (pancreatic extract).

Hepatitis E virus infection

This medicine is of animal (pig) origin. Although steps are taken during manufacturing to reduce the risk, the presence of hepatitis E virus in this medicine is possible. Hepatitis E is a virus that can be present in pigs, which can be spread to humans and may cause infection of the liver.

A study has suggested that people with cystic fibrosis who have taken this medicine may be more likely to have had hepatitis E in the past. However, this study has important limitations. For example, it is unclear when the past infection happened or what the source of the infection was.

As a precaution, if you have a weakened immune system and you are also taking high doses of this medicine, your doctor will tell you about the symptoms of infection with hepatitis E. Talk to your doctor if you develop signs of an infection especially fever, nausea, unusual or changes in stomach pain, or yellowing of the skin or eyes.

Tell your doctor if you have cystic fibrosis, and you take in excess of 10,000 lipase units per kilogram bodyweight per day and have unusual abdominal symptoms or changes in abdominal symptoms.

Talk to your doctor, if you are pregnant or trying to get pregnant (Norzyme can be used while breast-feeding).

Please tell your doctor, dietician or pharmacist if you think that you should not take Norzyme for any other reason.

Driving and using machines

It is unlikely that Norzyme will affect your ability to drive or operate tools or machines.

3. How to take Norzyme

Always follow your doctor or dietician´s advice on how many capsules to take. Check with your doctor or pharmacist if you are not sure.

Your dose is measured in ‚lipase units‘. Lipase is one of the enzymes in pancreas powder. Different strengths of Norzyme contain different amounts of lipase.

If your doctor advises you to increase the number of capsules you take, you should do so slowly. If you still have fatty stools or abdominal pain, talk to your doctor or dietician.

When to take Norzyme
Always take Norzyme during or immediately after a meal or a snack and drink plenty of water (see section 1).

How to take Norzyme
- Swallow the capsules whole or
- Open the capsules and mix the micropellets (without crushing) with acidic liquid (e.g. apple, orange or pineapple juice) or soft food (e.g. apple sauce or yoghurt). Swallow the mixture straight away, without chewing. Do not store the mixture.
- Drink plenty of liquid every day.
- Mixing with non-acidic food or liquid, crushing or chewing of the micropellets may cause irritation inside your mouth or change the way Norzyme works in your body.
- Do not hold Norzyme capsules or its content in your mouth.

How long to take Norzyme for
You should take your medicine until your doctor tells you to stop. Many patients will need to take pancreatic enzyme supplements for the rest of their lives.

If you take more Norzyme than you should
Drink plenty of water and talk to your doctor immediately.

If you forget to take Norzyme
Wait until your next meal and take your usual number of capsules. Do not try to make up for the number of capsules that you have missed. **Just take your next dose at the usual time.**

4. Possible side effects
Like all medicines, this medicine can cause side effects (unwanted effects or reactions), but not everybody gets them.

If you have severe or long-lasting abdominal pain, contact your doctor immediately.

If you notice any **unusual abdominal symptoms** while taking Norzyme – contact your doctor.

Very common side effects (may affect more than 1 out of 10 people)
- stomach pain

Common side effects (may affect more than 1 – 10 out of 100 people)
- constipation

- feeling or being sick
- diarrhoea
- bloating

Uncommon side effects (may affect more than 1 – 10 out of 1000 people)

- skin reactions, such as rash

During use, some patients have also experienced the following, the frequency of which is unknown:

- itching with or without a rash
- allergic reactions (which may be severe)
- severe or long-lasting abdominal pain (Fibrosing colonopathy)

At extremely high doses, some patients have had high levels of uric acid in their blood and urine.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Norzyme

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 label and carton after 'EXP'. The expiry date refers to the last day of that month.

Store below 25 °C.

After opening use within 4 months.

Keep the container tightly closed in order to protect from moisture.

Do not throw away any medicines via wastewater. 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 Norzyme contains

The active substance is pancreas powder (pancreatic extract) from pigs.

Each capsule contains

- 25,000 Ph. Eur. units lipase

- 18,750 Ph. Eur. units amylase
- 1,125 Ph. Eur. units protease

The other ingredients are:

Capsule contents:

Crospovidone
Microcrystalline cellulose
Highly dispersed silica
Magnesium stearate
Methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30 % (contains Methacrylic acid-ethyl acrylate copolymer (1:1), polysorbate 80, sodium laurilsulfate and water)
Triethyl citrate
Talc
Simeticon emulsion (contains simeticon, methyl cellulose, sorbic acid and water)
Montan glycol wax

Capsule shells:

Gelatine
Titanium dioxide (E171)
Iron oxides and hydroxides (E172)

What Norzyme looks like and contents of the pack

Norzyme are hard gelatine capsules (24.5 mm) with brown opaque cap and transparent body. They contain gastro-resistant micropellets of small size.

Amber glass bottle(s) in outer carton with:

50 gastro-resistant capsules, hard
100 gastro-resistant capsules, hard
200 (2x100) gastro-resistant capsules, hard

Not all pack sizes may be marketed.

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