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ZENTIVA

Package leaflet: Information for the user

Nutrizym 22

Pancreatin

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Nutrizym 22 is and what it is used for
2. What you need to know before you take Nutrizym 22
3. How to take Nutrizym 22
4. Possible side effects
5. How to store Nutrizym 22
6. Contents of the pack and other information

1. What Nutrizym 22 is and what it is used for

This medicine is given to patients who have a disorder of their pancreas. The pancreas is an organ situated in your abdomen near to your stomach.

The pancreas releases substances called enzymes into the small intestine (small bowel) to digest food. If you have a disorder such as cystic fibrosis or pancreatitis and your pancreas is not working properly you may need to take extra enzymes, so that your food is fully digested. Nutrizym 22 contains the active ingredient pancreatin, which includes the enzymes that you need.

2. What you need to know before you take Nutrizym 22

Do not take Nutrizym 22:

- if you have ever had an allergic reaction to pancreatin or any of the other ingredients of Nutrizym 22 (see list of ingredients in section 6)
- if you are allergic (hypersensitive) to pig (pork) products
- if you have cystic fibrosis and are 15 years old or younger

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Nutrizym 22

Hyperuricaemia (high levels of uric acid in the blood) and hyperuricosuria (excessive amounts of uric acid in the urine) can occur in cystic fibrosis patients. Pancreatin extracts contain small amounts of purine and if high doses of Nutrizym are given this may cause hyperuricaemia and hyperuricosuria.

Other medicines and Nutrizym 22

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Taking Nutrizym 22 with food and drink

Take the capsules with a meal or snack. Swallow the capsules whole with water. (See Section 3)

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Nutrizym 22 can be taken during breast-feeding.

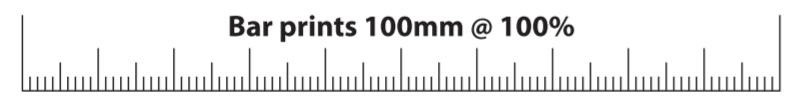
Important information about the ingredients of Nutrizym 22

Nutrizym 22 contains Castor Oil which may cause stomach upset and diarrhoea. This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Nutrizym 22

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Swallow the capsules whole with water with meals and snacks which are soft foods.

If you find that swallowing the capsules is difficult, remove the minitabets from their capsule and swallow them quickly with a small amount of acidic fluid or soft food. This could be apple sauce, yoghurt or any fruit juice with acidic pH (e.g., apple, orange or pineapple juice). You should not chew the minitabets because this damages the special coating on them. It is important that you drink plenty of fluid while you are on Nutrizym 22.



Recommended dose

Your doctor or dietician will tell you how many capsules you should take. The number taken will depend on your symptoms and on how well you respond to Nutrizym 22. If your doctor tells you to increase the number of capsules you are taking, make sure you do it gradually. Do not take more capsules than he has told you to.

If you take more Nutrizym 22 than you should

You may have an uncomfortable stomach, irritation/inflammation just outside of the anus, feel sick or vomit. If you do take a large overdose and feel unwell contact your doctor. Stop taking the capsules and keep well hydrated.

If you forget to take Nutrizym 22

It is important to take your capsules with snacks or meals. If you forget to do this, make sure you take your next dose with your next snack or meal. Do not take any capsules other than at meal or snack time.

If you stop taking Nutrizym 22

If you stop taking this medicine your condition may worsen. Do not do this unless your doctor has told you to. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following side effects with Nutrizym 22, STOP taking the capsules and contact your doctor immediately: A severe allergic reaction (frequency not known), such as itching, swelling of the face, lips, tongue, mouth, or throat, which may cause shortness of breath, wheezing, or difficulty breathing.

Other side effects include:

Very common:

- Abdominal pain. If you develop unusual stomach pains you should see your doctor.

Common:

- Nausea, vomiting, constipation, swollen belly, diarrhoea. If you develop a change in the regularity of your bowel habits, you should see your doctor.

Uncommon:

- Skin rash

Unknown frequency:

- A narrowing of the bowel can occur in cystic fibrosis patients who take large doses of some types of pancreatin. This may result in the need for an operation.
- Sometimes patients taking pancreatic enzymes develop a sore mouth or anus. If this happens to you and becomes a problem, talk to your doctor.
- Inflammation of the colon has been reported in children with cystic fibrosis taking pancreatic enzymes.
- Itching, hives

If you have any other side effects which persist whilst using Nutrizym 22 please tell your doctor or pharmacist straight away.

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 at: 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 Nutrizym 22

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

Do not store above 25°C.

It should be kept in the original container given to you by the pharmacist. You should keep the container tightly closed.

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

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 Nutrizym 22 contains

The active substance is pancreatin. Each capsule contains 313 mg of pancreatin as the active ingredient. This is equivalent to at least 22,000 units of lipase, 19,800 units of amylase and 1,100 units of protease.

The other ingredients are: castor oil, silicon dioxide, magnesium stearate, sodium carboxymethylcellulose, microcrystalline cellulose, simethicone emulsion, a methacrylic copolymer, talc and triethyl citrate. The capsules are made from gelatin and are coloured with titanium dioxide (E171), as well as iron oxide red and iron oxide yellow (E172).

What Nutrizym 22 looks like and contents of the pack

The active ingredient, pancreatin, is made into minitabets* which have been put inside hard, red and yellow gelatine capsules. The capsules are available in packs of 50, 100, 200 or 500 capsules. Not all pack sizes may be marketed.

*EURAND MINITABS – Trademark of Adare Pharmaceuticals S.r.l

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