

MEDICATION GUIDE
PERTZYE (pert-zye)
(pancrelipase)
delayed-release capsules

Read this Medication Guide before you start taking PERTZYE and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or treatment.

What is the most important information I should know about PERTZYE?

PERTZYE may increase your chance of having a rare bowel disorder called fibrosing colonopathy. This condition is serious and may require surgery. The risk of having this condition may be reduced by following the dosing instructions that your doctor gave you.

Call your doctor right away if you have any unusual or severe:

- stomach area (abdominal) pain
- bloating
- trouble passing stool (having bowel movements)
- nausea, vomiting, or diarrhea

Take PERTZYE exactly as prescribed by your doctor. Do not take more or less PERTZYE than directed by your doctor.

What is PERTZYE?

PERTZYE is a prescription medicine used to treat people who cannot digest food normally because their pancreas does not make enough enzymes due to cystic fibrosis or other conditions.

PERTZYE capsules contain a mixture of digestive enzymes including lipases, proteases and amylases from pig pancreas.

PERTZYE is safe and effective in children when taken as prescribed by your doctor.

What should I tell my doctor before taking PERTZYE?

Before you take PERTZYE, tell your doctor about all of your medical conditions, including if you:

- are allergic to pork (pig) products
- have a history of blockage of your intestines, or scarring or thickening of your bowel wall (fibrosing colonopathy)
- have gout, kidney disease, or high blood uric acid (hyperuricemia)
- have trouble swallowing capsules
- have any other medical condition

- are pregnant or plan to become pregnant. It is not known if PERTZYE will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if PERTZYE passes into your breast milk. You and your doctor should decide if you will take PERTZYE or breastfeed.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and dietary or herbal supplements.

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine.

How should I take PERTZYE?

- **Take PERTZYE capsules exactly as your doctor tells you.**
- You should not switch PERTZYE with any other pancreatic enzyme product without first talking with your doctor.
- Do not take more capsules in a day than the number your doctor tells you to take (total daily dose).
- Always take PERTZYE with a meal or snack and plenty of fluid. If you eat a lot of meals or snacks in a day, be careful not to go over your total daily dose.
- Your doctor may change your dose based on the amount of fatty foods you eat or based on your weight.
- **PERTZYE capsules should be swallowed whole. Do not crush or chew the PERTZYE capsules or their contents, and do not hold the capsule or capsule contents in your mouth.** Crushing, chewing or holding the PERTZYE capsules in your mouth may cause irritation in your mouth or change the way PERTZYE works in your body.

Giving PERTZYE to children and adults:

1. You should not divide the capsule contents into small amounts to give small doses of PERTZYE.
2. Swallow PERTZYE capsules whole and take them with enough liquid to swallow them right away.
3. If you have trouble swallowing capsules, open the capsules and mix the contents with a small amount of acidic food such as applesauce. Ask your doctor about other foods you can mix with PERTZYE.
4. If you mix PERTZYE with food, swallow it right after you mix it and drink plenty of water or juice to make sure the medicine is swallowed completely. Do not store PERTZYE that is mixed with food. Throw away any unused portion of capsule contents.
5. If you forget to take PERTZYE, wait until your next meal and take your usual number of capsules. Take your next dose at your usual time. **Do not take two doses at one time.**

What are the possible side effects of PERTZYE?

PERTZYE may cause serious side effects, including:

- See “**What is the most important information I should know about PERTZYE?**”
- **Irritation of the inside of your mouth.** This can happen if PERTZYE is not swallowed completely.
- **Increase in blood uric acid levels.** This may cause worsening of swollen, painful joints (gout) caused by an increase in your blood uric acid levels.
- **Allergic reactions,** including trouble breathing, skin rash, itching, or swollen lips.

Call your doctor right away if you have any of these symptoms.

The most common side effects of PERTZYE include:

- diarrhea
- upset stomach (indigestion)
- cough

Other possible side effects:

PERTZYE and other pancreatic enzyme products are made from the pancreas of pigs, the same pigs people eat as pork. These pigs may carry viruses. Although it has never been reported, it may be possible for a person to get a viral infection from taking pancreatic enzyme products that come from pigs.

Tell your doctor if you have any side effect that bothers you or does not go away.

These are not all of the possible side effects of PERTZYE. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to Digestive Care, Inc. at 1-800-882-5950.

How do I store PERTZYE?

- Store PERTZYE at room temperature 68°F to 77°F (20°C to 25°C).
- Keep PERTZYE in a dry place and in the original container.
- After opening the bottle, keep it tightly closed between uses to keep your medicine dry (protect it from moisture).
- The PERTZYE bottle contains a desiccant packet to help keep your medicine dry (protect it from moisture). **Do not eat or throw away the packet (desiccant) in your medicine bottle.**

Keep PERTZYE and all medicines out of the reach of children.

General information about the safe and effective use of PERTZYE

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use PERTZYE for a condition for which it was not prescribed. Do not give PERTZYE to other people to take, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about PERTZYE. If you would like more information, talk to your doctor. You can ask your pharmacist or doctor for information about PERTZYE that is written for health professionals.

For more information, go to www.digestivecare.com or call 1-800-882-5950.

What are the ingredients in PERTZYE?

Active ingredients: lipase, protease, amylase.

Inactive ingredients:

The hard gelatin capsules contain: sodium bicarbonate, sodium carbonate, cellulose acetate phthalate, sodium starch glycolate, diethyl phthalate, ursodiol, polyvinylpyrrolidone, and talc.

The imprinting ink on the 8,000 units of lipase; 28,750 units of protease; 30,250 units of amylase capsules contain: FD&C Blue #1, ethanol, methanol, n-butyl alcohol, propylene glycol, shellac and ammonium hydroxide.

The imprinting ink on the 16,000 units of lipase; 57,500 units of protease; 60,500 units of amylase capsules contain: FD&C Red #40, povidone, titanium dioxide, dehydrated alcohol, sodium hydroxide, butyl alcohol, propylene glycol, isopropyl alcohol, and shellac.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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