

Pertzye[®]

(pancrelipase)
Delayed-Release Capsules

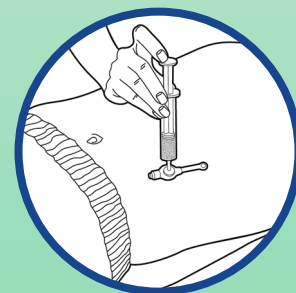
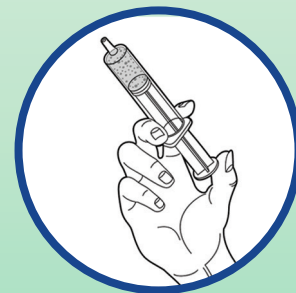
Containing Bicarbonate-Buffered Enteric-Coated Microspheres

Administering PERTZYE[®] (pancrelipase) through a gastrostomy tube



- PERTZYE 4,000 lipase units capsule contents may be given through a gastrostomy tube that is **size 14 French or larger**. Do not give PERTZYE through a gastrostomy tube smaller than size 14 French.
- Do not give more than the contents of 2 PERTZYE 4,000 lipase units capsules through a gastrostomy tube at a time.
- Give PERTZYE capsule contents-food mixture right away after it is prepared.

- 1** Place at least 2 teaspoons of applesauce, or other food recommended by your doctor, into a clean container.
- 2** Carefully open 1 or 2 of the PERTZYE capsules, depending on your prescribed dose, by grasping and slightly squeezing both ends of the capsule and then twisting and pulling the capsule apart. Pour the capsule contents onto the food in the clean container. Throw away the empty PERTZYE capsules.
- 3** Carefully mix the capsule contents evenly through the food. **Be careful not to crush the PERTZYE capsule contents when mixing.**
- 4** Remove the plunger from a 35 mL slip tip syringe. Cover the tip of the syringe with your finger.
- 5** Carefully spoon the PERTZYE capsule contents-food mixture into the slip tip syringe.
- 6** Replace the plunger partially back into the slip tip syringe.
- 7** Turn the slip tip syringe so the syringe tip is facing upward. Remove your finger from the tip of the slip tip syringe.
- 8** Gently shake or tap the slip tip syringe so that the PERTZYE capsule contents-food mixture moves down towards the plunger.
- 9** Carefully push up slowly on the plunger until the PERTZYE capsule contents-food mixture fills the syringe tip.
- 10** Connect the slip tip syringe directly into the gastrostomy tube feeding port.
- 11** Press on the plunger of the slip tip syringe using steady pressure to push all of the PERTZYE capsule contents-food mixture into the gastrostomy tube feeding port over 10 seconds to 12 seconds.
- 12** Flush the gastrostomy tube feeding port with about 10 mL of water.
- 13** If your prescribed dose is more than 2 capsules of PERTZYE, repeat steps 1 through 12, using only 1 or 2 PERTZYE capsules at a time, until the prescribed dose is given.



Indication

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 and adults when taken as prescribed by their doctor.

Important Safety Information

PERTZYE may increase the risk of having a rare bowel disorder called fibrosing colonopathy, especially if taken at a high dose in children with cystic fibrosis who are less than 12 years of age. This condition is serious and may require surgery. The risk of having fibrosing colonopathy may be reduced by following the dosing instructions that your doctor gives you. Call your doctor right away if you have any unusual or severe stomach area (abdominal) pain, bloating, trouble passing stools (constipation), nausea, vomiting, or diarrhea.

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. **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. Read the Medication Guide for instructions on how to take **PERTZYE** if you have trouble swallowing capsules.

The most common side effects of **PERTZYE** include diarrhea, upset stomach (indigestion), and cough. Other possible side effects of **PERTZYE** are irritation of the inside of your mouth; increase in blood uric acid levels, which may cause worsening of swollen, painful joints (gout); and allergic reactions, including trouble swallowing or breathing, skin rash, itching, or swelling of your face, eyes, lips, tongue, or throat. Call your doctor right away if you have any of these symptoms.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call **1-800-FDA-1088**.

Please see full Prescribing Information and Medication Guide at www.pertzye.com.