

MEDICATION GUIDE

PANCRELIPASE™ (pancrelipase) Delayed-Release Capsules

Read this Medication Guide before you start taking PANCRELIPASE 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 PANCRELIPASE?

- PANCRELIPASE 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 healthcare professional gave you. **Call your healthcare professional 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 PANCRELIPASE exactly as prescribed. Do not take more or less PANCRELIPASE than directed by your healthcare professional.

What is PANCRELIPASE?

PANCRELIPASE is a prescription medicine for people who cannot digest food normally because their pancreas does not make enough enzymes. PANCRELIPASE may help your body use fats, proteins and sugars from food.

PANCRELIPASE contains a mixture of digestive enzymes including lipases, proteases, and amylases from pig pancreas.

PANCRELIPASE is safe and effective in children.

What should I tell my doctor before taking PANCRELIPASE?

Before taking PANCRELIPASE, tell your doctor about all 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 PANCRELIPASE will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.

- are breast-feeding or plan to breast-feed. It is not known if PANCRELIPASE passes into your breast milk. You and your doctor should decide if you will take PANCRELIPASE 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 PANCRELIPASE? Take PANCRELIPASE exactly as your doctor tells you.

- Do not take more capsules in a day than the number your doctor tells you. (total daily dose).
- Always take PANCRELIPASE with a meal or snack. If you eat a lot of meals or snacks in a day, be careful not to go over your total daily dose.
- **Do not crush or chew the PANCRELIPASE capsules or its contents, and do not hold the capsule or contents in your mouth.** Crushing, chewing or holding the PANCRELIPASE Capsules in your mouth may cause irritation in your mouth or change the way PANCRELIPASE works in your body.

Giving Pancrelipase to children and adults

- Swallow PANCRELIPASE capsules whole and take them with enough liquid to swallow them right away.
- If you have trouble swallowing capsules, open the capsules and sprinkle the beads on a small amount of acidic food such as applesauce, pureed bananas or pears. Ask your doctor about other foods you can mix with PANCRELIPASE.
- If you sprinkle PANCRELIPASE on food, swallow it right after you mix it. Do not store PANCRELIPASE that is mixed with food.
- Swallow the PANCRELIPASE and food mixture right away followed with water or juice. Make sure the medicine is swallowed completely.
- If you forget to take PANCRELIPASE, call your healthcare professional or wait until your next meal and take your usual number of capsules. **Do not make up for missed doses.** Take your next dose at the usual time.

Giving PANCRELIPASE to infants (children up to 12 months):

1. Give PANCRELIPASE right before each feeding of formula or breast milk.
2. Do not mix PANCRELIPASE capsule contents directly into formula or breast milk.
3. Open the capsules and sprinkle the contents on a small amount of applesauce, pureed bananas or pears. These foods should be the kind found in baby food jars that you buy at the store, or other food recommended by your doctor. You may also sprinkle the contents directly into your child's mouth.
4. If you sprinkle the PANCRELIPASE on food, give the PANCRELIPASE and food mixture to your child right away.
5. Give your child enough liquid to completely swallow the PANCRELIPASE contents or the PANCRELIPASE and food mixture.

6. Look in your child's mouth to make sure that all of the medicine has been swallowed.

What are possible side effects of PANCRELIPASE?

PANCRELIPASE may cause serious side effects, including:

See **"What is the most important information I should know about PANCRELIPASE?"**

- Worsening of swollen, painful joints (gout) caused by an increase in your blood uric acid levels
- **Allergic reactions** including trouble with breathing, skin rashes, or swollen lips.

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

The most common side effects of PANCRELIPASE include

- Pain in your belly
 - Gas
 - Headache

Other Possible Side Effects

PANCRELIPASE 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 the possible side effects of PANCRELIPASE. 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 Eurand Pharmaceuticals, Inc. at 1-800-716-6507

How do I store PANCRELIPASE?

- Store PANCRELIPASE at room temperature (68° to 77°F; 20°C to 25°C). Avoid heat.
- After opening the bottle, keep it closed tightly between doses
- DO NOT eat or throw away the packet (desiccant) in your medicine bottle. This packet will protect your medicine from moisture.
- Store PANCRELIPASE in a dry place.

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

General information about PANCRELIPASE

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

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

What are the ingredients in PANCRELIPASE?

Active ingredient: lipase, protease, amylase

Inactive ingredients: croscarmellose sodium, hydrogenated castor oil, colloidal silicon dioxide, microcrystalline cellulose, magnesium stearate, hypromellose phthalate, talc, and triethyl citrate in hypromellose capsules. The imprinting ink on the capsules contains shellac, dehydrated alcohol, isopropyl alcohol, propylene glycol, n-butyl alcohol, strong ammonia solution, and FD&C Blue #2 aluminum lake C.I. 73015-E132.

PANCRELIPASE™ is subject of US Patent No. 7,658,918.

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