

MEDICATION GUIDE
PANCREAZE® (pan-kre-aze)
(pancrelipase)
delayed-release capsules

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

PANCREAZE may increase your chance of having a rare bowel disorder called fibrosing colonopathy especially if taken at a high dose for a long time in children with cystic fibrosis. 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 (constipation)
- nausea, vomiting, or diarrhea

Take PANCREAZE exactly as prescribed by your doctor. Do not take more PANCREAZE than directed by your doctor.

What is PANCREAZE?

PANCREAZE is a prescription medicine used to treat people who cannot digest food normally because their pancreas does not make enough enzymes.

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

PANCREAZE is safe and effective in adults and children.

Before taking PANCREAZE, 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.
- are breastfeeding or plan to breastfeed. It is not known if PANCREAZE passes into your breast milk. Talk to your doctor about the best way to feed your baby if you take PANCREAZE.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, 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 PANCREAZE?

- **Take PANCREAZE exactly as your doctor tells you.** Contact your doctor if you continue to have signs and symptoms of malabsorption (not absorbing nutrients from food) such as abdominal pain, bloating, fatty stools, or weight loss. Your dose may need to be changed.
- You should not switch PANCREAZE with any other pancreatic enzyme product without first talking to your doctor.
- Do not take more capsules in a day than the number your doctor tells you (total daily dose).
- **Always take PANCREAZE with a meal or snack** and enough liquid (water, juice breast milk, or formula) to swallow PANCREAZE completely. 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.
- **PANCREAZE capsules should be swallowed whole. Do not crush or chew PANCREAZE capsules or its contents, and do not hold the capsule contents in your mouth.** Crushing, chewing or holding the PANCREAZE capsules in your mouth may cause irritation in your mouth or change the way PANCREAZE works in your body.

Giving PANCREAZE to Infants (Children from Birth up to 12 Months of Age):

The two ways to give PANCREAZE to infants (children from birth to 12 months of age) are described below:

a) Giving with Acidic Soft Food

1. Before each breast-feeding session or each time you give 120 mL of formula, carefully open the capsule and sprinkle the entire contents of the capsule on a small amount of acidic food such as applesauce. These foods should be the kind found in baby food jars that you buy at the store, or other food recommended by your doctor.
2. Mix the capsule contents evenly through the food. Be careful not to crush the PANCREAZE capsule contents while mixing.
3. Give the PANCREAZE and food mixture to your infant right away. **Do not** store PANCREAZE that is mixed with food.
4. Give your infant enough formula or breastfeed your infant **right away** to completely swallow the PANCREAZE food mixture.
5. Look into your infant's mouth to make sure that all the medicine has been swallowed.
6. Throw away the empty PANCREAZE capsule.

b) Giving Directly Into Infant's Mouth Before Breast or Formula Feeding

1. Before each breast-feeding session or each time you give 120 mL of formula, carefully open the PANCREAZE capsule and sprinkle the capsule contents directly into the infant's mouth.
 2. **Do not** mix the PANCREAZE capsule contents directly into a bottle of breast milk or formula.
 3. Give your infant additional breast milk or formula **right after** PANCREAZE to completely swallow the PANCREAZE capsule contents.
 4. Look into your infant's mouth to make sure that all the medicine has been swallowed.
 5. Throw away the empty PANCREAZE capsule.
- If a dose is missed, give the next dose with the next feeding.

Giving PANCREAZE to Adults and Children Older than 12 Months of Age:

- Swallow PANCREAZE capsules whole and take them with enough liquid (water or juice) to swallow them **right away**.
- If you have trouble swallowing capsules follow these instructions for taking PANCREAZE with food:
 - Carefully open the capsules and sprinkle the entire contents on a small amount of acidic food such as applesauce. Ask your doctor about other foods you can mix with PANCREAZE.
 - If you sprinkle PANCREAZE on 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 PANCREAZE that is mixed with food.
 - If you forget to take PANCREAZE, call your doctor or wait until your next meal and take your usual number of capsules. Take your next dose at your usual time. **Do not make up for missed doses.**

What are the possible side effects of PANCREAZE?

PANCREAZE may cause serious side effects, including:

- See “**What is the most important information I should know about PANCREAZE?**”
- **Irritation of the inside of your mouth.** This can happen if PANCREAZE is not swallowed completely.
- **Increase in blood uric acid levels (hyperuricemia).** This may happen in people with gout, kidney problems, or those who take high doses of pancrelipase, the active ingredient in PANCREAZE. Call your doctor if you have pain, stiffness, redness or swelling in your joints.
- **Severe allergic reactions.** Severe allergic reactions have happened in people taking pancreatic enzyme products like PANCREAZE. Stop taking PANCREAZE and get emergency treatment right away if you have any of these symptoms: trouble with breathing, skin rashes, swollen lips, or itching.

The most common side effects of PANCREAZE include:

- stomach (abdominal area) problems including nausea and vomiting.

Other possible side effects of PANCREAZE:

PANCREAZE 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 PANCREAZE. 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 VIVUS LLC at 1-888-998-4887.

How should I store PANCREAZE?

- Store PANCREAZE at room temperature between 59°F and 77°F (15°C and 25°C). Avoid heat.
- Keep PANCREAZE in a dry place and in the original container.
- After opening the bottle, keep it tightly closed between uses.
- All PANCREAZE bottles contain a desiccant canister. **Do not** eat or throw away the desiccant canister in your medicine bottle. This canister will protect your medicine from moisture.

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

General information about PANCREAZE

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

You can ask your pharmacist or doctor for information about PANCREAZE that is written for healthcare professionals.

What are the ingredients in PANCREAZE?

Active Ingredient: lipase, protease, amylase

Inactive ingredients in all strengths of PANCREAZE: colloidal silicon dioxide, crospovidone, magnesium stearate, methacrylic acid ethyl acrylate copolymer, microcrystalline cellulose, montan glycol wax, simethicone emulsion, talc and triethyl citrate. The capsule shell contains hypromellose, titanium dioxide and iron oxide.

Imprint ink for PANCREAZE 2600 contains black iron oxide, shellac, propylene glycol, strong ammonia solution, potassium hydroxide.

Imprint ink for PANCREAZE 4200, 10500 and 16800 contains black iron oxide, shellac-glaze-45%, ammonium hydroxide, propylene glycol.

Imprint ink for PANCREAZE 21000 contains yellow iron oxide, shellac, strong ammonia solution, propylene glycol.

Imprint ink for PANCREAZE 37000 contains black iron oxide, shellac-glaze-45%, ammonium hydroxide, propylene glycol.

For more information go to www.pancreaze.net or call 1-888-998-4887.



Product of Germany

Finished Product Manufactured at:

Nordmark Pharma GmbH

25436 Uetersen, Germany.

Manufactured by:

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U.S. License No. 2197

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

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