

pancreaze[®]
(pancrelipase) DELAYED-RELEASE CAPSULES

Tony, age 53
Chronic pancreatitis patient.
Diagnosed with EPI.
Actor portrayal

With every meal
and snack, take control.

PANCREAZE...
THE SYMPTOMS OF EPI.SM

**Suffering from chronic gas,
stomach pain or diarrhea?**

PANCREAZE helps treat people who cannot digest food normally because their pancreas does not make enough enzymes — a condition called **Exocrine Pancreatic Insufficiency (EPI)**.¹

*Managed Markets Insight & Technology, LLC database as of February 2024. Certain plans may require prior authorization.

IMPORTANT SAFETY INFORMATION

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

PANCREAZE may increase your chance of having a serious, rare bowel disorder called fibrosing colonopathy that may require surgery.

Please read the PANCREAZE Medication Guide and the enclosed Full Prescribing Information.

Learn how PANCREAZE can help

Barry, age 57
Whipple surgery patient
Diagnosed with EPI.
Actor portrayal

With every meal
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PANCREAZE...

THE SYMPTOMS OF EPI.™

What you will find in this product brochure

- What is **Exocrine Pancreatic Insufficiency (EPI)** and what are its symptoms?
- What is **PANCREAZE** and how can it help?
- How to take **PANCREAZE** correctly

 **Ask your doctor if PANCREAZE could be right for you.**

REVIEW THE SAVINGS INSERT

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WAYS TO
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A free, comprehensive support program that offers a **broad range of support services and monthly savings.**

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IMPORTANT SAFETY INFORMATION

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

Fibrosing colonopathy has been reported with high dosages of pancreatic enzyme products, usually with use over a prolonged period of time and in pediatric patients with cystic fibrosis. Colonic stricture has been reported in pediatric patients less than 12 years of age.

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.

IMPORTANT SAFETY INFORMATION

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

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.

Please read the Medication Guide and the enclosed Full Prescribing Information.


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Understanding Exocrine Pancreatic Insufficiency (EPI)

People with EPI can't properly digest food^{2,3}

EPI is a condition that occurs when the pancreas is unable to provide the enzymes needed to digest food. When you have exocrine pancreatic insufficiency the body can't properly digest and absorb fats, proteins, and carbohydrates from the food you eat. This means that after you eat, food passes through your system without being fully digested.

Without these enzymes, patients with EPI suffer from:

- **Maldigestion:** Impaired breakdown of food into nutrients for the body
- **Malabsorption:** Inability to absorb these nutrients

People with EPI lack these pancreatic enzymes⁴

LIPASE: Works with bile (a fluid produced by the liver) to break down fats.

AMYLASE: Breaks down carbohydrates for energy.

PROTEASE: Breaks down proteins.

IMPORTANT SAFETY INFORMATION

What should I tell my doctor before taking PANCREAZE?

Tell your doctor 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

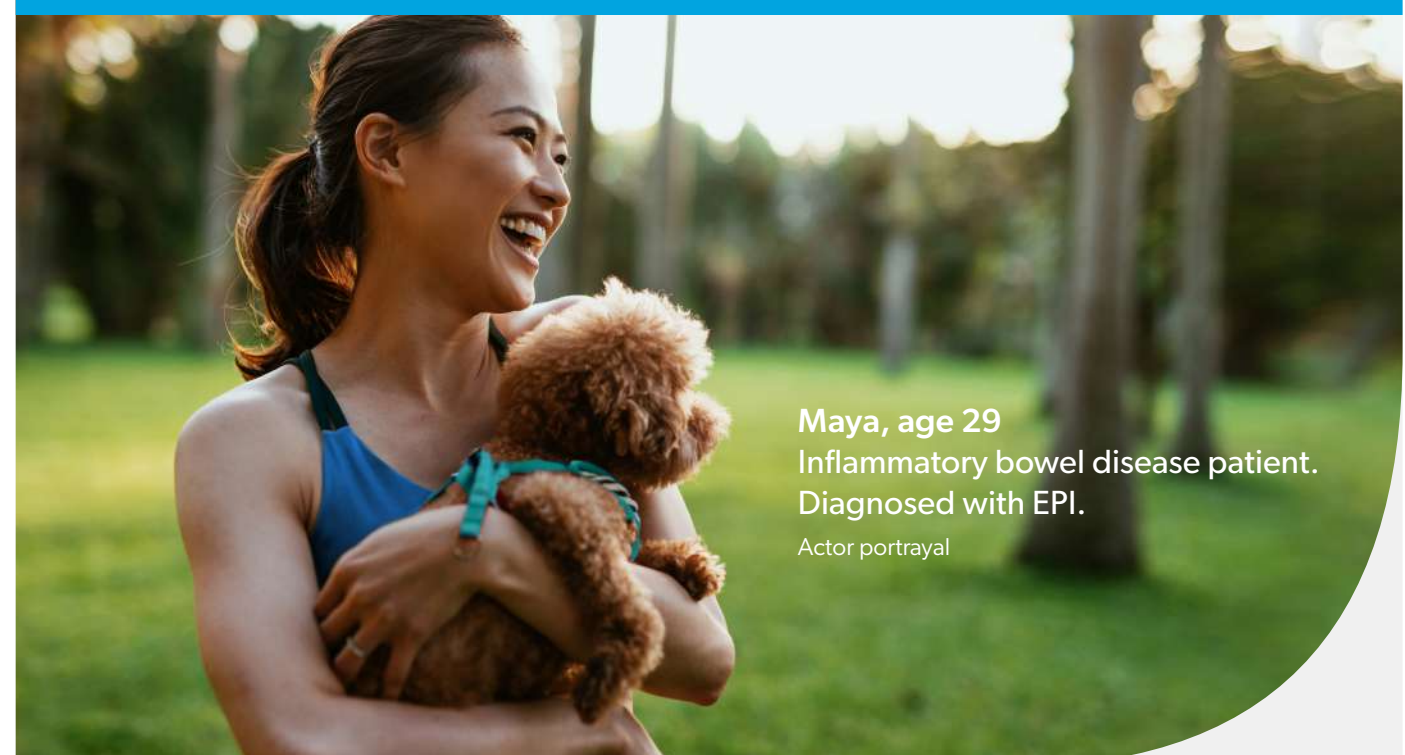
The most common conditions that lead to EPI

It's important to share your complete medical history with your doctor

In adults, chronic pancreatitis (CP) is the main cause of EPI in adults and is often diagnosed later in adulthood. As many as 8 in 10 adults with CP disorder develop EPI.^{3,5,6}

Cystic fibrosis (CF) is an inherited disease and the top cause of EPI in infants and children. Approximately 66% of CF patients develop EPI shortly after birth and his number jumps to 85% by one year of age.^{5,7,8}

Other conditions and surgical procedures can cause EPI^{3,9}



Maya, age 29
Inflammatory bowel disease patient.
Diagnosed with EPI.
Actor portrayal

Other causes of EPI include **celiac disease, diabetes, Inflammatory bowel disease (IBD), pancreatic cancer** as well as **surgery on the digestive tract**, including weight-loss surgery.

IMPORTANT SAFETY INFORMATION

What should I tell my doctor before taking PANCREAZE?

Tell your doctor if you:

- are breastfeeding or plan to breastfeed

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The symptoms of EPI

The most common symptoms of EPI are gastrointestinal — related to the stomach and digestion^{2,3}

People with EPI suffer from one or more troublesome chronic gastrointestinal and stomach issues.

Delays in treatment can impact your overall health and quality of life. Discuss with your doctor if you have **one or more of the following chronic symptoms:**



STOMACH PAIN: Gas and bloating resulting from poor digestion due to EPI can cause stomach pain.



GAS: Gas is made as the body breaks down food. Improper digestion can cause increased gas and flatulence.



BLOATING: Excess gas can cause the uncomfortable feeling of fullness in the abdomen.



DIARRHEA: Unabsorbed fats and nutrients in the small bowel, draw in water and cause diarrhea.



UNEXPLAINED WEIGHT LOSS: This can occur when the body can't absorb enough nutrients and fats.



GREASY STOOLS: Fat that isn't digested can cause greasy, foul-smelling stools that float.

IMPORTANT SAFETY INFORMATION

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

Real patient perspectives*



Maria, age 34
Ulcerative colitis patient.
Diagnosed with EPI.
Actor portrayal

In a recent online survey, patients reported that before being diagnosed with EPI, their most troublesome symptoms were: **diarrhea, stomach pain, oily stools and gas.**

These patients reported that prior to their diagnosis:

38%

Worried about interruptions from urgent, unpredictable symptoms

39%

Reported being upset not knowing what was causing their symptoms

***PANCREAZE Patient Survey:** Online survey conducted in January 2023. Responses from 133 EPI patients and caregivers of patients with EPI. Respondents were not remunerated for their participation in the survey.

IMPORTANT SAFETY INFORMATION

What are the possible side effects of PANCREAZE?

PANCREAZE may cause serious side effects, including:

- **A rare bowel disorder** called fibrosing colonopathy
- **Irritation of the inside of your mouth.** This can happen if PANCREAZE is not swallowed completely
- **Allergic reactions** including trouble with breathing, skin rashes, or swollen lips

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Gerry, age 42
Celiac patient.
Diagnosed with EPI.
Actor portrayal



What is PANCREAZE?

PANCREAZE is a pancreatic enzyme replacement therapy¹

PANCREAZE is a prescription medicine that replaces the enzymes that you or your child needs to digest food properly due to EPI.

The enzymes in **PANCREAZE** help the body digest food properly and absorb fat, protein and carbohydrates — which are needed for healthy growth, weight gain and improved nutritional health.

Clinically-proven results

PANCREAZE is clinically proven to improve EPI symptoms such as **abdominal pain, bloating, diarrhea, and greasy stools.**¹⁰

IMPORTANT SAFETY INFORMATION

What are the possible side effects of PANCREAZE?

PANCREAZE may cause serious side effects, including:

- **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. This may occur if you have gout or renal impairment. Contact your healthcare provider if you experience pain, stiffness, redness or swelling of your joints.

- **PANCREAZE** contains a mixture of digestive enzymes, including lipases, proteases, and amylases.
- **PANCREAZE** comes in the form of capsules. Inside, there are several tiny “beads” that contain enzymes. Each bead is covered with a special enteric coating.
- When the capsule enters the small intestine, the pH triggers the coating to dissolve and release the enzymes that are necessary to digest the food you eat.

The illustration does not show actual capsule color and contents.

IMPORTANT SAFETY INFORMATION

PANCREAZE may cause serious side effects, including:

- 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.

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Taking PANCREAZE

PANCREAZE comes in 6 strengths, ensuring flexible dosing for each patient's unique needs¹

Your doctor will individualize your dose based on age, weight and symptoms. **PANCREAZE's flexible dosing options ensure that you get the dose that's right for you.**

PANCREAZE STRENGTHS

(lipase units)



0.705"

CAPSULES ARE SHOWN AT RELATIVE SIZE

Your doctor will tell you how many capsules to take, and when, to help ensure you get the pancreatic enzymes you need, when you need them.

IMPORTANT SAFETY INFORMATION

The most common side effects include pain in your stomach (abdominal pain) and gas.

These are not all the side effects of PANCREAZE. Talk to your doctor about any side effect that bothers you or does not go away. You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to VIVUS LLC. at 1-888-998-4887.

You should take PANCREAZE with every meal and snack^{1,7}

Effective dosing strategies will vary by patient. Your doctor will advise you on how to take **PANCREAZE** — this may be the entire dose at once or divided throughout your meal. **Always take PANCREAZE exactly as recommended by your doctor.**

Splitting the dose over the course of a meal

Your doctor will advise you on how to take PANCREAZE. For some patients, splitting the dose over the course of a meal may be an optimal strategy for effective digestion.

START: Take 1 or more capsules at the beginning of the meal

CONTINUE: Take 1 or more capsules during the meal

COMPLETE: Take 1 or more capsules at the end of the meal

IMPORTANT SAFETY INFORMATION

How do I take PANCREAZE?

- Take PANCREAZE with meals or snacks.
- Swallow capsules whole.
- For adult and pediatric patients unable to swallow intact capsules, the capsule contents may be sprinkled on a small amount soft acidic food with a pH of 4.5 or less (e.g., applesauce).

Please read the Medication Guide and the enclosed Full Prescribing Information.

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Taking PANCREAZE

Ensure you take or administer PANCREAZE properly¹

Always take PANCREAZE exactly as recommended by your doctor.

FOR CHILDREN OVER 12 MONTHS AND ADULTS:

- Take PANCREAZE 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.



- Do not crush or chew the capsules or their contents or hold the capsule or 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.

FOR CAREGIVERS OF INFANTS (CHILDREN UP TO 12 MONTHS):

- Administer immediately prior to each feeding.
- Do not mix directly with formula or breast milk. Sprinkle on a small amount of acidic soft food with a pH of 4.5 or less (see next page) or sprinkle the capsule contents directly into the infant's mouth.



IMPORTANT SAFETY INFORMATION

How do I take PANCREAZE?

- For pediatric patients birth to 12 months of age, PANCREAZE capsules can also be opened, and the capsule contents sprinkled directly into the infant's mouth.

Unable to swallow the capsules?

If you or your child are unable to swallow the capsules, you can sprinkle the contents on soft acidic food (e.g., applesauce, orange juice, crushed blueberries).



Drink water or juice immediately after to ensure the medicine is swallowed completely.

Note: the capsule shown is not actual size and does not represent the exact size or color.

For additional information about PANCREAZE, including frequently asked questions, please visit:

[PANCREAZE.com](https://pancreaze.com)



REFERENCES: 1. PANCREAZE Full Prescribing Information. Campbell, CA: VIVUS LLC; 2024. 2. Cleveland Clinic. (n.d.). Exocrine Pancreatic Insufficiency (EPI). Retrieved from <https://my.clevelandclinic.org/health/diseases/21577-exocrine-pancreatic-insufficiency-epi> 3. Othman MO, et al. Introduction and practical approach to exocrine pancreatic insufficiency for the practicing clinician. *Int J Clin Pract.* 2018;72:e13066. 4. Cleveland Clinic. (n.d.). Pancreas. Retrieved from <https://my.clevelandclinic.org/health/body/21743-pancreas> 5. Lindkvist B. Diagnosis and treatment of pancreatic exocrine insufficiency. *World J Gastroenterol.* 2013;19(42):7258-7266. 6. The National Pancreas Foundation (n.d.). About Chronic Pancreatitis. Retrieved from <https://pancreasfoundation.org/patient-information/chronic-pancreatitis/> 7. Struyvenberg MR, et al. Practical guide to exocrine pancreatic insufficiency - breaking the myths. *BMC Med.* 2017;15(1):29. 8. The Cystic Fibrosis Foundation (n.d.). About Cystic Fibrosis. Retrieved from <https://www.cff.org/What-is-CF/About-Cystic-Fibrosis/> 9. Uribarri-Gonzalez L, et al. Exocrine pancreatic function and dynamic of digestion after restrictive and malabsorptive bariatric surgery: a prospective, cross-sectional, and comparative study. *Surg Obes Relat Dis.* 2021 Oct;17(10):1766-1772. 10. Trapnell BC, et al. Efficacy and safety of PANCREAZE[®] for treatment of exocrine pancreatic insufficiency due to cystic fibrosis. *J Cyst Fibros.* 2011;10(5):350-356.

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Jeanne, age 44
Type 1 diabetic.
Diagnosed with EPI.
Actor portrayal

With every meal
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THE SYMPTOMS OF EPI.™

Ask your doctor if **PANCREAZE** may be right for you.

- Clinically proven to improve chronic EPI symptoms such as abdominal pain, bloating, diarrhea, and greasy stools.¹⁰
- **PANCREAZE's** six flexible dosing options ensure targeted dosing for each patient's unique needs.¹
- Multiple ways to save! Refer to the insert on the inside cover.

IMPORTANT SAFETY INFORMATION

How do I take PANCREAZE?

- Consume sufficient liquids (juice, water, breast milk, or formula) and visually inspect an infant's mouth to ensure complete swallowing of PANCREAZE capsules or capsule contents.
- Do not crush or chew PANCREAZE capsules or capsule contents.

Please read the accompanying PANCREAZE Medication Guide and Full Prescribing Information and discuss any questions you have with your doctor.

VIVUS

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500167.06-USP 07/2024