



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

With every meal
and snack, take control.

PANCREAZE...

THE SYMPTOMS OF EPI.SM

DISCUSSION GUIDE

Could it be EPI?

Talk with your doctor about chronic gastrointestinal issues and predisposing conditions — ask if EPI (Exocrine Pancreatic Insufficiency) could be the cause

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. **See inside for Important Safety Information about PANCREAZE.**

Please note, the information presented here is intended for discussion purposes only and is not intended to be used as a substitute for a healthcare professional's medical expertise and judgment to diagnose, treat, or care for any particular patient.

We can help make the conversation easier

It's important to tell your doctor about the chronic GI symptoms you're experiencing

This guide can help you talk to your doctor about your medical background and what you are currently feeling. **Only your doctor can determine if your symptoms are due to EPI (Exocrine Pancreatic Insufficiency) or another condition.**

Make sure to mention all your symptoms, when you experience them, your medical history and any medications that you may be taking.

“This is embarrassing to say”

HELPFUL TIP

It's ok to say this as a way to signal how you feel.

The most common symptoms of EPI

When you have EPI, your body is missing the enzymes it needs to properly digest food. This can make meal and snack time uncomfortable. The most common symptoms are gastrointestinal.^{1,2}



STOMACH PAIN



DIARRHEA



UNEXPLAINED WEIGHT LOSS



GAS



BLOATING



GREASY STOOLS

Don't wait to speak up

Delays in treating EPI can impact your overall health and quality of life.² **Complete, print and bring this guide with you to your appointment, or have it ready for your telemedicine visit.**

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. 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.



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Are you at increased risk?

**Other conditions and surgical procedures
can put you at risk for developing EPI¹⁻⁸**

In adults, chronic pancreatitis (CP) is the main cause of EPI and is often diagnosed between 30-40 years of age. Cystic fibrosis (CF) is an inherited disease and the top cause of EPI in infants and children. However, 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.

The estimated prevalence of EPI by condition or surgical procedure

Gastrointestinal Conditions		Metabolic and Immunodeficiency Conditions		Bariatric Surgery	
Celiac Disease	12-30%	Diabetes Type 1	26-44%	BPD/DS*	75%
Crohn's Disease	14%	Diabetes Type 2	12-20%	Roux-en-Y Gastric Bypass†	9-31%
Inflammatory Bowel Disease	19-30%	HIV/AIDS	26-45%	Sleeve Gastrectomy	4%
Ulcerative Colitis	22%				

* This type of bariatric surgery (Biliopancreatic diversion with duodenal switch) changes the size of your stomach and the length of your small intestine.⁵

† This surgery reduces the size of your upper stomach to a small pouch. In one study, EPI was diagnosed in 9.1% of patients one year after Roux-en-Y, mini-omega or loop gastric bypass. In another study, 31% of patients were diagnosed with EPI 52 months after distal and proximal Roux-en-Y gastric bypass. The prevalence of EPI after bariatric surgery can vary based on the type and extent of the surgery. The likelihood of EPI after gastric banding is low, however after a sleeve gastrectomy, the neuronal network is impaired, and small percentage of patients with EPI can be expected (4.3%).⁶⁻⁸

Important Safety Information (cont.)

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.





Your symptoms and medical history

1. Have you recently been experiencing the following symptoms?

- | | | |
|---------------------------------------|--|---|
| <input type="checkbox"/> Stomach pain | <input type="checkbox"/> Bloating | Do you have difficulty holding bowel or have to rush to the bathroom? |
| <input type="checkbox"/> Gas | <input type="checkbox"/> Greasy stools | |
| <input type="checkbox"/> Diarrhea | <input type="checkbox"/> Unexplained weight loss | |
- Yes No

2. How recently did you start experiencing symptoms?

- | | | | |
|---|---|-----------------------------------|--------------------------------------|
| <input type="checkbox"/> 1 Month | <input type="checkbox"/> 3 Months | <input type="checkbox"/> 6 Months | Do your symptoms occur after eating? |
| <input type="checkbox"/> More than 6 months | <input type="checkbox"/> Unknown duration | | |
- Yes No

3. Does your medical history include conditions that affect the pancreas? Select all that apply.

- | | | |
|---|---|--|
| <input type="checkbox"/> Chronic pancreatitis | <input type="checkbox"/> Pancreatic cancer | <input type="checkbox"/> Cystic fibrosis |
| <input type="checkbox"/> Pancreatic surgery | <input type="checkbox"/> Type 1 or 2 diabetes | <input type="checkbox"/> None of these |

4. Does your medical history include conditions that affect your gastrointestinal system?

Select all that apply.

- | | | |
|---|---|--|
| <input type="checkbox"/> IBS (Irritable Bowel Syndrome) | <input type="checkbox"/> Ulcerative colitis | <input type="checkbox"/> None of these |
| <input type="checkbox"/> Crohn's disease | <input type="checkbox"/> Celiac disease | |

5. Are you taking any medications for your symptoms?

- Yes No

If yes, please list the medications you are taking:

Important Safety Information (cont.)

What should I tell my doctor before taking 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.





Talking about bowel movements and stools

People with EPI can experience a specific type of diarrhea called steatorrhea. This occurs when one has excessive amounts of fat in their stools. These bowel movements can be greasy, float, smell really bad, and be difficult to flush. Not all people with EPI experience this symptom.⁹

Use the following checklist to discuss your symptoms with your doctor.

- I am often interrupted by the need for urgent, unpredictable bowel movements
- It takes several flushes for the stool to go down (they float)
- My stools look like they're covered in a greasy film
- My stools look pale or gray
- An extremely foul smell lingers in the bathroom after I have a bowel movement
- I frequently experience diarrhea — my stools are consistently liquid or very soft
- My stools often stick to the side of the toilet bowl
- I see oil droplets floating in the toilet bowl after a bowel movement
- My stools appear bulky, foamy or frothy

Important questions to ask your doctor

- Could my symptoms be caused by EPI?
- Could my symptoms be related to something in my medical history?
- Could my symptoms be caused by something that I'm eating?
- Could my symptoms be caused by any medications that I'm taking?
- What can I do to improve my GI symptoms?

Important Safety Information (cont.)

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.
- **Allergic reactions** including trouble with breathing, skin rashes, or swollen lips



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

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These tips can help

- **Talk about the impact:** Let your doctor know how your symptoms are affecting your daily life.
- **Bring notes:** If you are feeling awkward describing your symptoms, write down details to share.

Important Safety Information (cont.)

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.

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.

How do I take PANCREAZE?

- Take PANCREAZE with meals or snacks.
- Swallow capsules whole.
- For 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).
- 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.
- 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.
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- Do not crush or chew PANCREAZE capsules or capsule contents.

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

REFERENCES: **1.** Cleveland Clinic. (n.d.). Exocrine Pancreatic Insufficiency (EPI). Retrieved from <https://my.clevelandclinic.org/health/diseases/21577-exocrine-pancreatic-insufficiency-epi> **2.** Othman MO, et al. Introduction and practical approach to exocrine pancreatic insufficiency for the practicing clinician. *Int J Clin Pract.* 2018;72:e13066. **3.** The National Pancreas Foundation (n.d.). About Chronic Pancreatitis. Retrieved from <https://pancreasfoundation.org/patient-information/chronic-pancreatitis/> **4.** Fousekis FS, Theopistos VI, Katsanos KH, Christodoulou DK. Pancreatic Involvement in Inflammatory Bowel Disease: A Review. *J Clin Med Res.* 2018;10(10):743-751. **5.** Mayo Clinic. (n.d.). Biliopancreatic diversion with duodenal switch (BPD/DS). Retrieved from <https://www.mayoclinic.org/tests-procedures/biliopancreatic-diversion-with-duodenal-switch/about/pac-20385180> **6.** Mayo Clinic. (n.d.). Gastric bypass (Roux-en-Y). Retrieved from <https://www.mayoclinic.org/tests-procedures/gastric-bypass-surgery/about/pac-20385189> **7.** 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. **8.** Vujasinovic M, et al. Pancreatic Exocrine Insufficiency after Bariatric Surgery. *Nutrients.* 2017 Nov 13;9(11): 1241. **9.** Cleveland Clinic. (n.d.). Steatorrhea. <https://my.clevelandclinic.org/health/symptoms/24049-steatorrhea-fatty-stool>

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