

DISCUSSION GUIDE

Could it be EPI?

Talking with your doctor about chronic gastrointestinal issues — and asking if Exocrine Pancreatic Insufficiency (EPI) could be the cause

Indication

PANCREAZE 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. PANCREAZE may help your body use fats, proteins, and sugars from food. **See the following pages for Important Safety Information**

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

Complete and share this guide with your doctor at your next appointment.

Don't feel embarrassed or delay the conversation about your symptoms. This guide can help you talk to your doctor about both 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.

When you have EPI, your body is missing the enzymes it needs to properly digest food, which can cause important nutrients to pass through the body unabsorbed. The most common symptoms of EPI are gastrointestinal — related to the stomach and digestion — and include:¹



STOMACH PAIN



DIARRHEA



UNEXPLAINED WEIGHT LOSS



GAS



BLOATING



GREASY STOOLS

Don't wait to speak up. It's important to tell to your doctor about the chronic GI symptoms you're experiencing. Delays in treating EPI can impact your overall health and quality of life. 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. The risk of having this condition may be reduced by following the dosing instructions that your healthcare provider gave you.



Your symptoms and medical history	
1. Have you recently been experiencing the following symptoms?	
 Stomach pain Gas Do you have difficulty holding bowel or have to rush to the bathroom? Diarrhea Unexplained weight loss Yes No 	
2. How recently did you start experiencing symptoms?	
1 Month	
More than 6 months Unknown duration Yes No	
3. Does your medical history include conditions that affect the pancreas? Select all that apply. Chronic pancreatitis Pancreatic cancer Cystic fibrosis Type 1 or 2 diabetes None of these	
4. Does your medical history include conditions that affect your gastrointestinal system?	
Select all that apply. IBS (Irritable Bowel Syndrome) Ulcerative colitis None of these Crohn's disease Celiac disease	
5. Are you taking any medications for your symptoms?	
If yes, please list the medications you are taking:	

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 <u>unusual or severe</u> stomach area (abdominal) pain, bloating, trouble passing stool (having bowel movements), nausea, vomiting, or diarrhea.





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.²

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

- Is it possible I have a GI condition?
- 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 EPI?
- 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.)

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)



These tips can help

Having an honest, open conversation with your doctor about your chronic gastrointestinal issues can help them properly diagnose and treat you. **Try to be specific — the more detailed you can be, the better.** Use these tips to help overcome any embarrassment or awkwardness when discussing your symptoms or the tests your doctor may recommend.

- 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.)

What should I tell my doctor before taking PANCREAZE? (cont.)

Tell your doctor if you:

- 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

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

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

Do not crush or chew the PANCREAZE capsules or their contents, and do not hold the capsule or contents in your mouth. Take PANCREAZE exactly as your doctor tells you. Read the Medication Guide for directions on how to give PANCREAZE to adults and children (children older than 12 months).

Read the Medication Guide for directions on how to give PANCREAZE to infants (children up to 12 months).

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

REFERENCES: 1. Othman MO, et al. Introduction and practical approach to exocrine pancreatic insufficiency for the practicing clinician. Int J Clin Pract. 2018;72:e13066. **2.** Cleveland Clinic. (n.d.). Steatorrhea. https://my.clevelandclinic.org/health/symptoms/24049-steatorrhea-fatty-stool



