

**■ PANCREASE® MT 2   ■ PANCREASE® MT 4   ■ PANCREASE® MT 10**  
**■ PANCREASE® MT 16   ■ PANCREASE® MT 20**

**Pancrelipase Delayed-Release Capsules**

Read this carefully before you start taking Pancrease MT and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Pancrease MT.

**Serious Warnings and Precautions**

- Pancreatic enzyme products, including Pancrease MT, have been associated with strictures of the ileo-caecum and large intestine if given at high doses chronically to patients with cystic fibrosis.
- Pancrease MT cannot be substituted (unit for unit) with other pancreatic enzyme products because they are biological products and, therefore, differ in their manufacturing processes, formulations, exact composition, enzymatic activities, stability and bioactivity in the small intestine, so the response of the patient to the estimated dose must be monitored and adjusted as necessary.

**What is Pancrease MT used for?**

- for the treatment of pancreatic insufficiency attributed to cystic fibrosis, chronic pancreatitis, or any other medically defined pancreatic disease that might require pancreatic enzyme therapy, as determined by your doctor.

**How does Pancrease MT work?**

Pancrease MT is classified as a digestant. This means that Pancrease MT capsules contain enzymes that help in the digestion of food. These enzymes – called lipase, amylase and protease – break down the fats, proteins and starches in food and convert them into substances that can be easily used by the body. The tiny microtablets inside each capsule of Pancrease MT contain a certain amount of each of these enzymes. Because these microtablets are enteric coated, they are not digested by the stomach but work directly in the lower gastrointestinal tract. Once they have done their work, any undigested enzymes are simply passed out of the body in the feces (bowel movements).

**What are the ingredients in Pancrease MT?**

Medicinal ingredients:  
 Each capsule of enteric-coated porcine pancreatic enzyme concentrate microtablets contains

Pancrease® MT 2	Lipase 2,600 USP Units Amylase 10,850 USP Units Protease 6,200 USP Units
Pancrease® MT 4	Lipase 4,200 USP Units Amylase 17,500 USP Units Protease 10,000 USP Units
Pancrease® MT 10	Lipase 10,500 USP Units Amylase 43,750 USP Units Protease 25,000 USP Units
Pancrease® MT 16	Lipase 16,800 USP Units Amylase 70,000 USP Units Protease 40,000 USP Units
Pancrease® MT 20	Lipase 21,000 USP Units Amylase 61,000 USP Units Protease 37,000 USP Units

Non-medicinal ingredients: colloidal anhydrous silica, 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 (except for Pancrease® MT 20).

**Pancrease MT comes in the following dosage forms:**

- ■ Pancrease® MT 2 Capsules
- ■ Pancrease® MT 4 Capsules
- ■ Pancrease® MT 10 Capsules
- ■ Pancrease® MT 16 Capsules
- ■ Pancrease® MT 20 Capsules

**Do not use Pancrease MT if:**

- you have known hypersensitivity to porcine protein, pancreatic enzymes or any excipients; and/or
- during acute pancreatitis or the acute exacerbation of chronic pancreatitis.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Pancrease MT. Talk about any health conditions or problems you may have, 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 Pancrease MT will harm your unborn baby
- are breast-feeding or plan to breast-feed. It is not known if Pancrease MT passes into your breast milk. You and your doctor should decide if you will take Pancrease MT or breast-feed.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**How to take Pancrease MT:**

- Pancrease MT capsules and capsule contents should not be crushed or chewed. Capsules should be swallowed whole. If there is a problem with taking capsules whole (younger children may sometimes have a problem swallowing the capsules) the capsules may be opened up and the microtablets mixed with soft food which does not require chewing e.g., applesauce, dessert gelatin, etc., but not milk, ice cream, other dairy products or custard because the pH is too high. If you sprinkle Pancrease MT on food, give the Pancrease MT and food mixture to your child right away. Do not store Pancrease MT that is mixed with food.

- Your doctor will do special tests periodically and, if necessary, will adjust the number of capsules you or your child take. Do not change the number of capsules unless your doctor tells you to. Taking too many capsules over a long period of time may lead to complications.

- You should always drink plenty of fluids to maintain your body's fluid balance.

**Usual dose:**

**Adults and Children:**

Because Pancrease MT acts as a digestant, the capsules should be taken with, and only with, meals and snacks. Your doctor will tell you how many capsules to take with each meal and with snacks. The doctor may instruct you to start with a small number of capsules and gradually increase the number until the best effect is achieved. **Follow your healthcare professional's instructions carefully.** The number of capsules you should take is calculated according to age, weight and the results of special tests. Usually, a certain number of capsules are taken with each meal and half that number are taken with each snack. The total number of capsules per day usually reflects 3 meals and 2 snacks per day.

**Infants < 12 months:**

Give Pancrease MT right before each feeding of formula or breast milk. Do not mix Pancrease MT capsule contents directly into formula or breast milk. Do not store Pancrease MT that is mixed with food. **Follow your doctor's instructions carefully.**

**Overdose:**

If you think you, or a person you are caring for, have taken too much Pancrease MT, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you forget to take Pancrease MT, call your healthcare provider 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 possible side effects from using Pancrease MT?**

These are not all the possible side effects you may have when taking Pancrease MT. If you experience any side effects not listed here, tell your healthcare professional.

The most common adverse reactions are abdominal discomfort, constipation and dermatitis. Other gastrointestinal reactions are less common and include abnormal stool and diarrhea. Nausea and vomiting have been reported but are not common. With high doses, perianal irritation and inflammation have been reported.

Allergic or hypersensitivity reactions of the skin have been reported.

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

**Serious side effects and what to do about them**

Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Rare</b>			
Allergic Reaction (trouble breathing, skin rash, swollen lips)	✓		✓
Abdominal pain, bloating, nausea, vomiting, diarrhea and/or constipation	✓		✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

**Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

**Storage:**

**You should keep the capsules in the bottle with the lid tightly closed. Store the bottle in a dry place with a temperature of 10°C to 25°C (room temperature). Do not refrigerate.**

Keep out of reach and sight of children.

**If you want more information about Pancrease MT:**

- Talk to your healthcare professional  
 Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website [[www.vivuspharma.ca](http://www.vivuspharma.ca)], or by calling 1-888-998-4887.
- For questions, concerns, or the full product monograph go to:  
[www.vivuspharma.ca](http://www.vivuspharma.ca) or contact the manufacturer, VIVUS LLC, at 1-888-998-4887

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