

PART III: CONSUMER INFORMATION

PrPANCREASE® MT 4
PrPANCREASE® MT 10
PrPANCREASE® MT 16

Pancrelipase Delayed-Release Capsules

This leaflet is Part III of a three-part "Product Monograph" published when PANCREASE® MT was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about PANCREASE® MT. Contact your doctor or pharmacist if you have any questions about the drug.

cellulose, montan glycol wax, simethicone emulsion, talc, and triethyl citrate. The capsule shell contains gelatin, titanium dioxide, sodium lauryl sulfate, sorbitan monolaurate, and iron oxide.

What dosage forms it comes in:
 PANCREASE® MT 4 Capsules
 PANCREASE® MT 10 Capsules
 PANCREASE® MT 16 Capsules

WARNINGS AND PRECAUTIONS

ABOUT THIS MEDICATION

What the medication is used for:

PANCREASE® MT is 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.

What it does:

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).

When it should not be used:

PANCREASE® MT should not be used 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.

What the medicinal ingredient is:

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

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

What the nonmedicinal ingredients are:

colloidal anhydrous silica, crospovidone, magnesium stearate, methacrylic acid ethyl acrylate copolymer, microcrystalline

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.

BEFORE you use PANCREASE® MT talk to your doctor or pharmacist 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 doctor about all the medicines you take, including prescription and nonprescription drugs, natural health products, vitamins, or herbal supplements.

PROPER USE OF THIS MEDICATION

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 doctor'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:

In case of drug overdose, contact a health care practitioner, 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.**

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor		Stop taking drug and call your doctor immediately
	Only if severe	In all cases	
Very rare abdominal pain, bloating, nausea, vomiting, diarrhea and/or constipation	T		T
Rare Allergic reactions : • trouble breathing • skin rash • swollen lips	T		T

This is not a complete list of side effects. For any unexpected effects while taking PANCREASE® MT, contact your doctor or pharmacist.

HOW TO STORE IT

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-25°C (room temperature). Do not refrigerate.

The PANCREASE® MT 4 bottle contains a desiccant canister. DO NOT eat or throw away the canister (desiccant) in your medicine bottle. This packet will protect your medicine from moisture.

Keep out of the sight and reach of children.

If you have any questions that have not been answered in this leaflet, please consult your doctor, pharmacist or other health care professional.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

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- \$ Report online at www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting
 - \$ Call toll-free at 1-866-234-2345
 - \$ Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect® Canada Web site at www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For questions, concerns, or the full product monograph go to:
www.janssen.com/canada
or contact the manufacturer, Janssen Inc., at:
1-800-567-3331 or 1-800-387-8781.

This leaflet was prepared by
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