

# **PANCRECARB<sup>®</sup>** (pancrelipase)

Delayed-Release Capsules – Bicarbonate-Buffered and Enteric-Coated Microspheres

## **Signs of Malabsorption**

**If you notice any of the following signs of malabsorption, please contact your healthcare provider.**

- 1. Greasy and Oily Stools**
- 2. Increased Frequency of Stools Per Day**
- 3. Large Bulky Stools**
- 4. Distention or Bloating**
- 5. Excessive or Foul Smelling Gas**

**With meals, take \_\_\_\_\_ PANCRECARB<sup>®</sup> (pancrelipase) MS-\_\_\_\_\_**

**With snacks, take \_\_\_\_\_ PANCRECARB<sup>®</sup> (pancrelipase) MS-\_\_\_\_\_**

**Please contact your Healthcare Provider with any questions or concerns.**

**Name:** \_\_\_\_\_ **Phone#:** \_\_\_\_\_

See product information on reverse side.

## **Helpful Information On Pancreatic Enzymes**

- Enzymes should be taken before and/or during meals and snacks.
- Enzymes should be taken with liquid and swallowed whole. They should not be chewed or crushed.
- If unable to take in capsule form, be sure to open capsule and empty contents of capsule into applesauce or other acidic food. To ensure complete swallowing, immediately follow with a glass of water or juice.
- Enzymes should not sit in food. They should be administered immediately. Failure to do so may lead to inactivation of enzymes.
- Store enzymes at a controlled room temperature below 77° F in a dry place. Do not refrigerate enzymes. Keep enzymes away from heat and humidity. Keep bottle tightly closed.
- Monitor expiration dates closely. Do not mix old capsules with new capsules.
- Enzymes should be taken before milk products are consumed.
- "Grazing" food behavior can make enzyme dosing difficult; therefore, discrete meals and snacks are recommended.
- For prolonged meals, enzymes may need to be distributed throughout the meal. This is a good practice, especially at buffets or parties.
- Discuss dosing of enzymes and meal content with your healthcare provider.
- The following are some foods that may not need enzymes: fruits, juice drinks, soft drinks, tea, black coffee, hard candy, fruit snacks, jelly beans, gum, non-dairy popsicles, freezer pops.

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# PANCRECARB<sup>®</sup>

(pancrelipase)

Delayed-Release Capsules – Bicarbonate-Buffered and Enteric-Coated Microspheres

**DESCRIPTION:** PANCRECARB<sup>®</sup> (pancrelipase) Delayed-Release Capsules are a clear, gelatin, orally administered capsule containing small enteric-coated microspheres of buffered pancreatic enzymes of lipase, amylase and protease, isolated and concentrated from porcine pancreatic glands. The enzyme containing microspheres are coated with a pH-sensitive enteric coating to provide protection against gastric inactivation of the buffer stabilized enzymes during gastric passage.

Each PANCRECARB<sup>®</sup> MS-4 capsule contains:

Lipase	4,000 U.S.P. Units
Amylase	25,000 U.S.P. Units
Protease	25,000 U.S.P. Units

Each PANCRECARB<sup>®</sup> MS-8 capsule contains:

Lipase	8,000 U.S.P. Units
Amylase	40,000 U.S.P. Units
Protease	45,000 U.S.P. Units

Each PANCRECARB<sup>®</sup> MS-16 capsule contains:

Lipase	16,000 U.S.P. Units
Amylase	52,000 U.S.P. Units
Protease	52,000 U.S.P. Units

Inactive ingredients include sodium carbonate, sodium bicarbonate, cellulose acetate phthalate, diethyl phthalate, gelatin, sodium carboxymethyl starch, polyvinylpyrrolidone, talc, ursodiol, and other trace ingredients.

**CLINICAL PHARMACOLOGY:** The buffer stabilized pancreatic enzymes in PANCRECARB<sup>®</sup> (pancrelipase) Delayed-Release Capsules are enteric-coated with a gastric acid resistant polymer to protect the enzymes during gastric transit into the duodenum. After being swallowed, the gelatin capsules dissolve in the gastric juice within minutes and the released microspheres disperse with food in the stomach. Upon passing into the duodenum, the enteric-coated PANCRECARB<sup>®</sup> microspheres are activated at approximately pH 5.5, discharge their digestive enzymes and the released digestive enzymes help to re-establish the natural digestive conditions in the intestine. The digestive enzymes in PANCRECARB<sup>®</sup> act locally in the gastrointestinal tract. The carbonate buffer provides an optimized pH-condition in the microenvironment surrounding the microspheres for the digestive enzymes to hydrolyze fats into glycerol and fatty acids, proteins into peptides and amino acids, and starch into dextrins and maltose. Once the digestive enzymes accomplish their catalytic function to hydrolyze food, the digestive enzymes may be inactivated by anti-enzymes, which are secreted by the intestinal mucosa, or digested by proteases. The digested enzyme fragments may be absorbed from the intestine and subsequently excreted in the urine. The inactivated enzymes are excreted in the feces. PANCRECARB<sup>®</sup> (pancrelipase) Delayed-Release Capsules are effective in controlling steatorrhea and its consequences.

**INDICATIONS AND USAGE:** PANCRECARB<sup>®</sup> (pancrelipase) Delayed-Release Capsules are indicated for patients with exocrine pancreatic enzyme insufficiency such as: cystic fibrosis, chronic pancreatitis due to alcohol use or other causes, post-pancreatectomy and post-gastrointestinal bypass surgery (e.g. Billroth II gastroenterostomy).

**CONTRAINDICATIONS:** PANCRECARB<sup>®</sup> (pancrelipase) Delayed-Release Capsules are contraindicated in patients known to be hypersensitive to pork protein or any other ingredient of this product.

**WARNINGS:** Should hypersensitivity occur during the course of treatment, discontinue medication and treat symptomatically. Cases of intestinal stricture and blockage requiring surgical decompression have been reported in cystic fibrosis patients, especially in patients with a history of intestinal complications such as meconium ileus equivalent, short bowel syndrome, surgery or Crohn's disease, who were taking high potency lipase pancreatic enzyme preparations (i.e., those labeled as containing more than 20,000 lipase units per capsule). If symptoms suggestive of gastrointestinal obstruction occur, the possibility of bowel strictures should be considered including evaluation of pancreatic enzyme therapy. Patients receiving lipase doses of >2,500 U.S.P. Units/kg/meal should be re-evaluated and the lipase dose either be reduced by 50% or titrated down gradually to the lowest effective clinical dose as determined by 72 hours fecal fat excretion determinations.

**PRECAUTIONS:** GENERAL – TO PROTECT ENTERIC COATING, MICROSPHERES SHOULD NOT BE CRUSHED OR CHEWED. The microsphere-containing capsules should be swallowed with liquids at the start of a meal. Where swallowing of capsules is difficult, the capsules may be carefully opened and the microspheres shaken onto a small quantity of soft food such as jelly, jello, or applesauce, which does not require chewing, and swallowed immediately, followed by a glass of water or juice to ensure complete swallowing. Prolonged contact of the microspheres with foods having a pH greater than 5.5 can weaken the integrity of the protective enteric coat and compromise the potency of the enzymes.

**INFORMATION FOR PATIENTS:** Patients should be advised that:

- PANCRECARB<sup>®</sup> enteric-coated microspheres should not be crushed or chewed
- PANCRECARB<sup>®</sup> enteric-coated microspheres capsules should be swallowed with liquids at the start of a meal
- PANCRECARB<sup>®</sup> enteric-coated microspheres, when removed from the gelatin capsule, should be swallowed immediately and not be retained in the mouth
- Liquids should be consumed liberally while dosing with PANCRECARB<sup>®</sup>

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** Long-term studies in animals have not been performed to evaluate carcinogenic potential of PANCRECARB<sup>®</sup> (pancrelipase) Delayed-Release Capsules.

**Pregnancy/Reproduction:** Pregnancy Category C. Diethyl phthalate, an enteric coating component of PANCRECARB<sup>®</sup> (pancrelipase) Delayed-Release Capsules has been shown to be teratogenic in rats following high intraperitoneal dosing. When this coating was given orally to rats up to 100 times the human dose, however, no teratogenic or embryocidal effects were observed. There were no adequate and well-controlled studies in pregnant women. PANCRECARB<sup>®</sup> (pancrelipase) Delayed-Release Capsules should be used during pregnancy only if the potential benefits justify the potential risk to the fetus.

**Nursing mothers:** It is not known whether pancrelipase is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when PANCRECARB<sup>®</sup> is administered to a nursing mother.

**ADVERSE REACTIONS:** The most frequently reported adverse reactions to pancrelipase-containing products are gastrointestinal in nature, which may include nausea, vomiting, bloating, cramping, constipation or diarrhea. Less frequently, allergic-type reactions have also been observed. Extremely high doses of exogenous pancreatic enzymes have been reported to be associated with hyperuricemia and hyperuricemia. High strength pancrelipase preparation (i.e., those labeled as containing more than 20,000 lipase units per capsule) has been associated with colonic strictures.

**DOSING, DURATION OF THERAPY:** Dosage should be individualized and adjusted according to fat intake, severity of steatorrhea and the severity of the exocrine pancreatic insufficiency. Begin therapy with one or two capsules with meals or snacks and adjust dosage according to symptoms. Dose increases, if required, should be made slowly, with careful monitoring of response and symptomatology. It is important to ensure adequate hydration of patients at all times while taking PANCRECARB<sup>®</sup>. Patients with pancreatic enzyme insufficiency should consume a high-caloric diet with unrestricted fat intake, which is appropriate for age and clinical symptomatology.

**HOW SUPPLIED:** PANCRECARB<sup>®</sup> (pancrelipase) Delayed-Release Capsules are supplied as follows:

- PANCRECARB<sup>®</sup> MS-4 (clear, hard gelatin capsule imprinted in green with "DCI" and "PANCRECARB<sup>®</sup> MS-4") in bottles of 100 (NDC 59767-002-01).
- PANCRECARB<sup>®</sup> MS-8 (clear, hard gelatin capsule imprinted in blue with "DCI" and "PANCRECARB<sup>®</sup> MS-8") in bottles of 100 (NDC 59767-001-01).
- PANCRECARB<sup>®</sup> MS-8 (clear, hard gelatin capsule imprinted in blue with "DCI" and "PANCRECARB<sup>®</sup> MS-8") in bottles of 250 (NDC 59767-001-02).
- PANCRECARB<sup>®</sup> MS-16 (clear, hard gelatin capsule imprinted in red with "DCI" and "PANCRECARB<sup>®</sup> MS-16") in bottles of 100 (NDC 59767-003-01).
- PANCRECARB<sup>®</sup> MS-16 (clear, hard gelatin capsule imprinted in red with "DCI" and "PANCRECARB<sup>®</sup> MS-16") in bottles of 250 (NDC 59767-003-02).

**STORAGE:** Store at controlled room temperature below 25°C (77°F) in a dry place. Do not refrigerate. Do not expose capsules to humid air. Keep bottle tightly closed. Dispense capsules in a tight container.

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U.S. Patents Nos. 5,260,074, 5,302,400, 5,324,514, 5,460,812, 5,578,304, 5,750,104 and patents pending.