

PART III: CONSUMER INFORMATION

PrCREON MINIMICROSPHERES®

(pancreatin)

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

ABOUT THIS MEDICATION

What the medication is used for:

CREON MINIMICROSPHERES® is used by children and adults for the treatment of pancreatic exocrine insufficiency attributed to cystic fibrosis, chronic pancreatitis, or any other medically defined pancreatic disease that might require pancreatic enzyme therapy, as determined by the doctor, including but not limited to cystic fibrosis (a rare inherited disorder), acute pancreatitis (an attack of acute inflammation of the pancreas) or chronic pancreatitis (chronic inflammation of the pancreas), pancreatic surgery/pancreatectomy, gastrectomy (surgical removal of all or part of the stomach), pancreatic cancer, gastrointestinal bypass surgery (e.g. Billroth II gastroenterostomy) (surgical opening between the stomach wall and intestine), ductal obstruction of the pancreas or common bile duct (e.g. from tumor) and Shwachman-Diamond Syndrome (genetic disorder).

What it does:

CREON MINIMICROSPHERES® is intended as replacement therapy when your pancreas, which produces enzymes necessary to digest fat, protein and sugars, has stopped functioning or is not functioning as it should be. The medical term for this condition is pancreatic exocrine insufficiency. Symptoms of pancreatic exocrine insufficiency include steatorrhea (excess of fat in stools).

CREON MINIMICROSPHERES® contains an enzyme mixture that helps you digest food. The enzymes are taken from pig pancreas glands.

CREON MINIMICROSPHERES® contains small granules which slowly release the pancreatic enzymes in your gut (gastro-resistant granules, called minimicrospheres).

The enzymes in CREON MINIMICROSPHERES® work by digesting food as it passes through the gut. You should take CREON MINIMICROSPHERES® during or after a meal or snack. This will allow the enzymes to mix thoroughly with the food.

When it should not be used:

CREON MINIMICROSPHERES® should not be used:

- If you have known hypersensitivity or allergy to porcine protein, pancreatic enzymes or to any other ingredient in this product.

What the medicinal ingredient is:

The medicinal ingredient in CREON MINIMICROSPHERES® is pancreatin. CREON MINIMICROSPHERES® is a mixture of pancreatic enzymes (lipase, amylase and protease).

What the important non-medicinal ingredients are:

CREON MINIMICROSPHERES® MICRO contains cetyl alcohol, dimethicone 1000, hypromellose phthalate, macrogol 4000 and triethyl citrate.

CREON MINIMICROSPHERES® 10, 20, and 35 contains cetyl alcohol, dimethicone 1000, gelatin, hypromellose phthalate, iron oxides, macrogol 4000, sodium lauryl sulphate, titanium dioxide and triethyl citrate.

CREON MINIMICROSPHERES® 25 contains cetyl alcohol, dimethicone 1000, gelatin, hypromellose phthalate, iron oxides, macrogol 4000, sodium lauryl sulphate, and triethyl citrate.

What dosage forms it comes in:

CREON MINIMICROSPHERES® MICRO is available as round, light brown gastro-resistant granules (minimicrospheres), with 5,000 Ph. Eur. units of lipase, 5,100 Ph. Eur. units of amylase, and 320 Ph. Eur. units of protease per spoonful (100 mg).

CREON MINIMICROSPHERES® 10 is available as brown and transparent capsules. They contain gastro-resistant granules (minimicrospheres) with 10,000 Ph. Eur. units of lipase, 11,200 Ph. Eur. units of amylase, and 730 Ph. Eur. units of protease per capsule.

CREON MINIMICROSPHERES® 20 is available as brown and transparent capsules. They contain gastro-resistant granules (minimicrospheres) with 20,000 Ph. Eur. units of lipase, 22,400 Ph. Eur. units of amylase, and 1,460 Ph. Eur. units of protease per capsule.

CREON MINIMICROSPHERES® 25 is available as Swedish orange and transparent capsules. They contain gastro-resistant granules (minimicrospheres) with 25,000 Ph. Eur. units of lipase, 25,500 Ph. Eur. units of amylase, and 1,600 Ph. Eur. units of protease per capsule.

CREON MINIMICROSPHERES® 35 is available as red brown and transparent capsules. They contain gastro-resistant granules (minimicrospheres) with 35,000 Ph. Eur. units of lipase, 35,700 Ph. Eur. units of amylase, and 2,240 Ph. Eur. units of protease per capsule.

WARNINGS AND PRECAUTIONS**Serious Warnings and Precautions**

- A rare bowel condition called “fibrosing colonopathy”, where your gut is narrowed, has been reported in patients with cystic fibrosis taking high doses of pancreatic enzymes. As a precaution, consult your doctor if you experience any unusual abdominal symptoms or any change in abdominal symptoms, especially if you are taking more than 10,000 units of lipase/kg body weight/day or more than 4,000 units of lipase/gram fat intake.

CREON MINIMICROSPHERES® and other pancreatic enzyme products are made from the pancreas of pigs, the same pigs used for food. 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.

BEFORE you use CREON MINIMICROSPHERES® talk to your doctor or pharmacist if you:

- are allergic to pork (pig) products
- have a history of intestinal blockage of your intestines or scarring or thickening of your bowel wall (fibrosing colonopathy)
- have any other medical condition
- are pregnant or might become pregnant
- are breast-feeding or plan to breast-feed
- have trouble swallowing capsules

Talk to your doctor about all the drugs you are taking before taking CREON MINIMICROSPHERES®.

INTERACTIONS WITH THIS MEDICATION

No interaction studies have been performed.

PROPER USE OF THIS MEDICATION

Do not switch CREON MINIMICROSPHERES® with any other pancreatic enzyme product without first talking to your doctor.

Usual dose:

Your dose is measured in ‘lipase units’. Lipase is one of the enzymes in CREON MINIMICROSPHERES®.

Different strengths of pancreatic enzymes may contain different amounts of lipase.

Always follow your doctor’s advice on how much CREON MINIMICROSPHERES® to take.

Your doctor will adjust your dose to suit you. It will depend on:

- your illness
- your weight
- your diet
- how much fat is in your stools.

If you still have fatty stools or other stomach or gut problems (gastrointestinal symptoms), talk to your doctor as your dose may need to be adjusted.

Cystic fibrosis

- The usual starting dose for infants is 2,000 to 5,000 lipase units for each feeding (usually 120 mL). CREON MINIMICROSPHERES® MICRO can be given to infants.
- The usual starting dose for children under 4 years of age is 1,000 lipase units per kilogram body weight per meal. Usually, half the standard dose is given with snacks.
- The usual starting dose for children 4 years of age and over, adolescents and adults is 500 lipase units per kilogram body weight per meal. Usually, half the standard dose is given with snacks.

Other problems with your pancreas

- The usual dose for a meal is between 25,000 and 80,000 lipase units.
- The usual dose for a snack is half the dose for a meal.
- In certain conditions, such as with acute pancreatitis, CREON MINIMICROSPHERES® should be taken when food intake has started again.

When to take CREON MINIMICROSPHERES®

Always take CREON MINIMICROSPHERES® during or after a meal or a snack. This will allow the enzymes to mix thoroughly with the food and digest it as it passes through the gut.

How to take CREON MINIMICROSPHERES®

- Swallow the capsules whole.
- Do not crush or chew the capsules.
- If it is difficult to swallow the capsules, open them carefully and add the granules to a small amount of soft acidic food or mix them with acidic liquids. Acidic soft foods could for example be apple sauce or yogurt. Acidic liquids could be apple, orange or pineapple juice. Alternatively the minimicrospheres can be mixed with a small amount of milk on a (weaning) spoon and given to the infant immediately. The minimicrospheres should not be added to a baby’s bottle.
- Swallow the mixture immediately, without crushing or chewing and drink some water or juice. Mixing with non-acidic foods, or crushing or chewing of the granules may cause irritation in your mouth or change the way CREON MINIMICROSPHERES® works in your body.
- Do not hold CREON MINIMICROSPHERES® capsules or its content in your mouth.

- Do not store the mixture.
- As a general rule, drink plenty of liquid every day.

How long to take CREON MINIMICROSPHERES® for

Take CREON MINIMICROSPHERES® until your doctor tells you to stop. Many patients will need to take CREON MINIMICROSPHERES® for the rest of their lives.

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.

If you know or suspect that you have taken more of this product than you normally do, or notice any unusual symptoms, contact your doctor or nearest hospital emergency department immediately. Ensure that you are adequately hydrated during this time by drinking plenty of fluids.

Extremely high doses of pancreatic enzymes have sometimes caused too much uric acid in the urine (hyperuricosuria) and in the blood (hyperuricaemia).

Missed Dose:

If a dose of this medication has been missed, take your next dose at the usual time, with your next meal. Do not try to make up for the dose that you have missed.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Unknown frequency	Allergic reactions (anaphylactic reactions) - trouble breathing - swollen lips		√	√
	Fibrosing colonopathy (abnormal narrowing of the gut)		√	√

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

Tell your healthcare professional if you have any side effect that bothers you or does not go away.

HOW TO STORE IT

Keep out of the reach of children.

Store at temperatures not exceeding 25°C in a tightly-closed container to protect from moisture.

Once opened, store at temperatures not exceeding 25°C, keep the container tightly-closed to protect from moisture and use within 6 months.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, CREON MINIMICROSPHERES® can cause side effects, although not everybody gets them. The following side effects were seen during studies in patients taking CREON MINIMICROSPHERES®.

- Very common: Pain in stomach (abdomen)
- Common: Bloating (abdominal distention), constipation, diarrhea*, nausea, vomiting
- Uncommon: Rash
- Frequency unknown: Severe itching (pruritus) and hives (urticaria)

* These may be due to the condition you are taking CREON MINIMICROSPHERES® for. During studies, the number of patients taking CREON MINIMICROSPHERES® who had pain in their stomach or diarrhea was similar or lower than in patients not taking CREON MINIMICROSPHERES®.

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:

- Report on line at:
www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at <http://www.healthcanada.gc.ca/medeffect>

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

The most recent version of this document plus the full Product Monograph, prepared for health professionals can be found at:

www.mylan.ca

or by contacting the sponsor, BGP Pharma ULC, Etobicoke, Ontario, M8Z 2S6 at:
1-844-596-9526

This leaflet was prepared by BGP Pharma ULC.

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