

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrCREON MINIMICROSPHERES®

pancreatin

Read this carefully before you start taking **CREON MINIMICROSPHERES®** 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 **CREON MINIMICROSPHERES®**.

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.

What is CREON MINIMICROSPHERES® 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).]

How does CREON MINIMICROSPHERES® work?

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.

What are the ingredients in CREON MINIMICROSPHERES®?

Medicinal ingredients: Pancreatin [a mixture of pancreatic enzymes (lipase, amylase and protease)].

Non-medicinal ingredients:

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

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

CREON MINIMICROSPHERES® 25 and 35: cetyl alcohol, dimethicone 1000, gelatin, hypromellose phthalate, iron oxides, macrogol 4000, sodium lauryl sulphate and triethyl citrate.

CREON MINIMICROSPHERES® comes in the following dosage forms:

CREON MINIMICROSPHERES® MICRO: round, light brown gastro-resistant granules (minimicrospheres), 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: brown and transparent capsules, 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: brown and transparent capsules 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: Swedish orange and transparent capsules 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: burnt orange and transparent capsules 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.

Do not use CREON MINIMICROSPHERES® if:

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

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take CREON MINIMICROSPHERES®. Talk about any health conditions or problems you may have, including 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

Other warnings you should know about:

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.

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

No interaction studies have been performed with CREON MINIMICROSPHERES®.

How to take CREON MINIMICROSPHERES®:

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

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.

Overdose:

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).

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

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.

What are possible side effects from using CREON MINIMICROSPHERES®?

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

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 Severe itching (pruritus) and hives (urticaria)
unknown:

* 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®.

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	
UNKNOWN FREQUENCY			
Allergic reactions (anaphylactic reactions) - trouble breathing - swollen lips		√	√
Fibrosing colonopathy (abnormal narrowing of the gut)		√	√

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:

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.

Keep out of reach and sight of children.

If you want more information about CREON MINIMICROSPHERES®:

- 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.mylan.ca], or by calling 1-844-596-9526.

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