

MEDICATION GUIDE

CREON® (krē 'ŏn) (pancrelipase) Delayed-Release Capsules

Read this Medication Guide before you start taking CREON and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or treatment.

What is the most important information I should know about CREON?

CREON may increase your chance of having a rare bowel disorder called fibrosing colonopathy. This condition is serious and may require surgery. The risk of having this condition may be reduced by following the dosing instructions that your doctor gave you. **Call your doctor right away if you have any unusual or severe:**

- stomach area (abdominal) pain
- bloating
- trouble passing stool (having bowel movements)
- nausea, vomiting, or diarrhea

Take CREON exactly as prescribed. Do not take more or less CREON than directed by your doctor.

What is CREON?

CREON is a prescription medicine used to treat people who cannot digest food normally because their pancreas does not make enough enzymes due to cystic fibrosis, swelling of the pancreas that lasts a long time (chronic pancreatitis), removal of some or all of the pancreas (pancreatectomy), or other conditions. CREON may help your body use fats, proteins, and sugars from food.

CREON contains a mixture of digestive enzymes including lipases, proteases, and amylases from pig pancreas.

What should I tell my doctor before taking CREON?

Before taking CREON, tell your doctor about all your medical conditions, 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 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 CREON will harm your unborn baby.
- are breast-feeding or plan to breast-feed. It is not known if CREON passes into your breast milk.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine.

How should I take CREON?

- **Take CREON exactly as your doctor tells you.**
- You should not switch CREON with any other pancreatic enzyme product without first talking to your doctor.
- Do not take more capsules in a day than the number your doctor tells you to take (total daily dose).
- Always take CREON with a meal or snack and enough liquid to swallow CREON completely. If you eat a lot of meals or snacks in a day, be careful not to go over your total daily dose.
- Your doctor may change your dose based on the amount of fatty foods you eat or based on your weight.
- **Do not crush or chew CREON capsules or its contents, and do not hold the capsule or capsule contents in your mouth.** Crushing, chewing or holding the CREON capsules in your mouth may cause irritation in your mouth or change the way CREON works in your body.

Giving CREON to infants (children up to 12 months)

1. Give CREON right before each feeding of formula or breast milk.
2. Do not mix CREON capsule contents directly into formula or breast milk.
3. Open the capsules and sprinkle the contents directly into your infant's mouth or mix the contents in a small amount of room temperature acidic soft food such as applesauce. These foods should be the kind found in baby food jars that you buy at the store, or other food recommended by your doctor.
4. If you sprinkle the CREON on food, give the CREON and food mixture to your child right away. Do not store CREON that is mixed with food.
5. Give your child enough liquid to completely swallow the CREON contents or the CREON and food mixture.
6. Look in your child's mouth to make sure that all of the medicine has been swallowed.

Giving CREON to children and adults

1. Swallow CREON capsules whole and take them with enough liquid to swallow them right away.
2. If you have trouble swallowing capsules, open the capsules and sprinkle the contents on a small amount of room temperature acidic food such as applesauce. Ask your doctor about other foods you can mix with CREON.
3. If you sprinkle CREON on food, swallow it right after you mix it and drink enough water or juice to make sure the medicine is swallowed completely. Do not store CREON that is mixed with food.
4. If you forget to take CREON, call your doctor 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 the possible side effects of CREON?

CREON may cause serious side effects, including:

- See **“What is the most important information I should know about CREON?”**
- **Irritation of the inside of your mouth.** This can happen if CREON is not swallowed completely.
- **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.**
- **Allergic reactions including trouble with breathing, skin rashes, or swollen lips.**

Call your doctor right away if you have any of these symptoms.

The most common side effects of CREON include:

- Blood sugar increase (hyperglycemia) or decrease (hypoglycemia)
- Pain in your stomach (abdominal area)
- Frequent or abnormal bowel movements
- Gas
- Vomiting
- Dizziness
- Sore throat and cough

Other Possible Side Effects:

CREON and other pancreatic enzyme products are made from the pancreas of pigs, the same pigs people eat as pork. 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 doctor if you have any side effect that bothers you or that does not go away.

These are not all the side effects of CREON. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

You may also report side effects to Abbott Laboratories at 1-800-241-1643.

How should I store CREON?

- Store CREON at room temperature below 77°F (25°C). Avoid heat.
- You may store CREON at a temperature between 77°F to 104°F (25°C to 40°C) for up to 30 days. Throw away any CREON stored at these temperatures for more than 30 days.
- Keep CREON in a dry place and in the original container.
- After opening the bottle, keep it closed tightly between uses to protect from moisture.

Keep CREON and all medicines out of the reach of children.

General information about CREON

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use CREON for a condition for which it was not prescribed. Do not give CREON to other people to take, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about CREON. If you would like more information, talk to your doctor. You can ask your doctor or pharmacist for information about CREON that is written for healthcare professionals. For more information, go to www.creon-us.com or call toll-free [1-800-241-1643].

What are the ingredients in CREON?

Active Ingredient: lipase, protease, amylase

Inactive Ingredients: cetyl alcohol, dimethicone, hypromellose phthalate, polyethylene glycol, and triethyl citrate.

The shells of the CREON 6,000 USP units of lipase, 12,000 USP units of lipase, and 24,000 USP units of lipase strengths contain: gelatin, red iron oxide, sodium lauryl sulfate, titanium dioxide, and yellow iron oxide.

In addition:

The shells for the CREON 3,000 USP units of lipase contain titanium dioxide and hypromellose.

The shells of the 6,000 USP units of lipase strength capsules contain FD&C Blue No. 2.

The shells of the 12,000 USP units of lipase strength capsules contain black iron oxide.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured for:

Abbott Laboratories
North Chicago, IL 60064, U.S.A.

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