

MEDICATION GUIDE
CREON® (krē 'ōn)
(pancrelipase)
delayed-release capsules, for oral use

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 especially if taken at a high dose for a long time in children with cystic fibrosis. This condition is serious and may require surgery. The risk of having this condition may be reduced by following the dosing instructions that your healthcare provider gave you.

Call your healthcare provider 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 healthcare provider.

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.

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

CREON is safe and effective in adults and children.

Before you take CREON, tell your healthcare provider about all your medical conditions, including 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.
- are breastfeeding or plan to breastfeed. It is not known if CREON passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take CREON.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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

How should I take CREON?

- **Take CREON exactly as your healthcare provider tells you.** Contact your healthcare provider if you continue to have signs and symptoms of malabsorption (not absorbing nutrients from food) such as abdominal pain, abdominal distention, bloating, fatty stools, or weight loss. Your dose may need to be changed.
- You should not switch CREON with any other pancreatic enzyme product without first talking to your healthcare provider.
- Do not take more capsules in a day than the number your healthcare provider tells you to take (total daily dose).
- **Always take CREON with a meal or snack** and enough liquid (water, juice, breast milk, or formula) 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 healthcare provider may change your dose based on the amount of fatty foods you eat or based on your weight.
- **CREON capsules should be swallowed whole. 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 Adults and Children Older than 12 Months of Age

- Swallow CREON capsules whole without crushing or chewing them.
- If you have trouble swallowing capsules:
 - Carefully open the capsules and sprinkle the entire contents on small amounts of acidic soft food such as applesauce, bananas, or plain Greek yogurt. Ask your healthcare provider about other foods you can use.
 - Mix the capsule contents with the soft food. Do not crush the contents.
 - Swallow the mixture right away. Do not save it for later use.
- Drink enough water or juice right away to make sure the medicine is swallowed completely.
- If you forget to take CREON, 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.**

Giving CREON to Infants (Children from Birth up to 12 Months of Age)

- Give CREON right before each breastfeeding or feeding formula.
- Do not mix CREON capsule contents directly into formula or breast milk.
- Carefully open the capsule and do one of the following:
 - Sprinkle the entire contents directly into your child's mouth **or**
 - Mix the entire contents in a small amount of acidic soft food such as applesauce, bananas, or plain Greek yogurt as described in the previous section. These foods should be the kind found in baby food jars that you buy at the store, or other food recommended by your healthcare provider. Give the mixture to your child right away. Do not save it for later use.
- Give your child additional breast milk or formula **right after** CREON to completely swallow the medicine. Look in your child's mouth to make sure that it was all swallowed.
- If a dose is missed give the next dose with the next feeding.

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 (hyperuricemia).** This may happen in people with gout, kidney problems, or those who take high doses of pancrelipase, the active ingredient in CREON. Call your healthcare provider if you have pain, stiffness, redness or swelling of your joints.
- **Severe allergic reactions.** Severe allergic reactions have happened in people taking pancreatic enzyme products like CREON. Stop taking CREON and get emergency treatment right away if you have any of these symptoms: trouble with breathing, skin rashes, swollen lips, or itching.

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 healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of CREON. **Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.**

You may also report side effects to AbbVie Inc. at 1-800-633-9110.

How should I store CREON?

- Store CREON at room temperature between 59°F to 77°F (15°C to 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. If there is a moisture-absorbing packet (desiccant) in the bottle, keep it in the bottle. Do not eat it or throw it away.

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

General information about the safe and effective use of 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.

You can ask your healthcare provider or pharmacist for information about CREON that is written for healthcare professionals.

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 for the CREON 3,000 USP units of lipase strength capsules contain hypromellose and titanium dioxide. They also may contain carrageenan and potassium chloride.

The shells of the CREON 6,000 USP units of lipase strength capsules may contain gelatin, hypromellose, carrageenan, potassium chloride, sodium lauryl sulfate, titanium dioxide, FD&C Blue No. 1, FD&C Blue No. 2, red iron oxide, and yellow iron oxide.

The shells of the CREON 12,000 USP units of lipase strength capsules may contain gelatin, hypromellose, carrageenan, potassium chloride, sodium lauryl sulfate, titanium dioxide, black iron oxide, red iron oxide, and yellow iron oxide.

The shells for the CREON 24,000 USP units of lipase strength capsules may contain gelatin, hypromellose, carrageenan, potassium chloride, sodium lauryl sulfate, titanium dioxide, red iron oxide, and yellow iron oxide.

The shells of the CREON 36,000 USP units of lipase strength capsules may contain gelatin, hypromellose, carrageenan, potassium chloride, sodium lauryl sulfate, titanium dioxide, FD&C Blue No. 1, and FD&C Blue No. 2.

Manufactured by:
AbbVie Inc.
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For more information, go to www.creon-us.com or call toll-free (1-800-633-9110).