

17.4 FDA-Approved Medication Guide

MEDICATION GUIDE

**CREON® (krē 'ōn)
(pancrelipase)
Delayed-Release Capsules**

Read this Medication Guide before you or your child start taking CREON and each time you or your child get a prescription refilled. There may be new information. This information does not take the place of talking with your healthcare professional about your medical condition or your 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 healthcare professional gave you. Call your healthcare professional right away if you have any unusual or severe stomach area (abdominal) pain.
- **Take CREON exactly as prescribed. Do not take more or less CREON than directed by your healthcare professional.**

What is CREON?

CREON is a prescription pancreatic enzyme medicine used to improve food digestion in people who cannot digest food properly because they have exocrine pancreatic insufficiency. CREON contains a mixture of digestive enzymes (including lipases, proteases, and amylases) from pig pancreas.

CREON is safe and effective in children.

What should I tell my healthcare professional before taking CREON?

Tell your healthcare professional if you:

- are allergic to pork (pig) products.
- have a history of intestinal blockage or a condition called fibrosing colonopathy.
- have gout, kidney disease, or a condition called high blood uric acid (hyperuricemia).
- have trouble swallowing capsules.
- are pregnant or planning 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 healthcare professional about all the medicines you take**, including prescription and nonprescription medicines, vitamins, and dietary or herbal supplements.

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

How should I take CREON?

- **Take CREON exactly as instructed by your healthcare professional.**

Infants (up to 12 months)

Contents of the capsule may be put directly in the infant's mouth or in a small amount of applesauce and administered (or given) just prior to feeding the infant breast milk or formula. Do not mix CREON capsule contents directly into formula or breast milk prior to administration. Care should be taken to ensure that the entire administered dose is swallowed and not retained in the mouth, to avoid irritation of the mouth.

Children and Adults

- Always take CREON during a meal or a snack and follow it with sufficient fluid.
- If you forget to take CREON, call your healthcare professional or wait until your next meal and take your usual number of capsules. **Do not make up for missed doses.** Take your next dose at the usual time.
- If you or your child takes more CREON than directed, call your healthcare professional right away.

- Swallow CREON whole. Do not crush or chew the contents of the capsules.

If you have trouble swallowing capsules, you can add the contents of an open capsule directly onto your food. To do so, carefully open the capsules and sprinkle the contents on a small amount of applesauce at room temperature as described below. Swallow the soft food right away without chewing and follow with water or juice.

- A. Hold the capsule upright so that you can read the word CREON on the capsule.



- B. Carefully twist off the top portion of the capsule over the food you plan to eat.



- C. Sprinkle the contents of the capsule onto the soft food. Do not crush the contents of the capsules.



- D. Swallow the CREON-soft food right away without chewing and follow with water or juice to make sure the contents of the capsules are swallowed completely.



What are the possible side effects of CREON?

CREON may cause serious side effects, including:

- CREON may increase your chance of having a rare bowel disorder called fibrosing colonopathy. See “What is the most important information I should know about CREON?”
- increase in blood uric acid levels, for example, worsening of gout, or painful, swollen joints. Call your healthcare professional right away if you have any of these symptoms.
- allergic reactions. For example, symptoms of an allergic reaction include: trouble with breathing, skin rashes, or swollen lips. Call your healthcare professional right away if you have any of these symptoms.

The most common side effects include:

- gassiness (flatulence)
- stomach area (abdominal) pain
- headache
- dizziness

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

These are not all the side effects of CREON. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/Medwatch. You may also report side effects to Solvay Pharmaceuticals, Inc. at 1-800-241-1643.

How should I store CREON?

- Store CREON at room temperature (up to 25°C or 77°F) for up to 12 weeks after the bottle is opened.
- If you store CREON at temperatures greater than room temperature (up to 40°C or 104°F), throw away after 30 days.
- Store CREON in the container you were given by the pharmacy.
- Keep the bottle closed tightly.
- Protect the bottle from moisture.

- **Keep CREON and all medicines out of 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.

This Medication Guide summarizes the most important information about CREON. If you would like more information, talk to your healthcare professional. You can ask your healthcare professional 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: pancrelipase

Inactive Ingredients: cetyl alcohol, dimethicone, gelatin, hypromellose phthalate, polyethylene glycol, red iron oxide, sodium lauryl sulfate, titanium dioxide, triethyl citrate, and yellow iron oxide. In addition, the 6,000 strength contains FD&C Blue No. 2 and the 12,000 strength contains black iron oxide. The imprinting ink on the capsule contains dimethicone, 2-ethoxyethanol, shellac, soya lecithin, and titanium dioxide.

Additional information about pancreatic enzymes

CREON and other pancreatic enzyme products are made from pancreatic organs of pigs used for food. There is a theoretical risk of contracting a viral infection from pig-derived medicines, but no human illness has been reported.

The risk of fibrosing colonopathy, increased blood uric acid levels, and the theoretical risk of viral transmission is present with all pancreatic enzyme products including CREON.

You should report any change in condition or illness to your healthcare professional.

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Manufactured for Solvay Pharmaceuticals, Inc., Marietta, GA 30062, U.S.A.

1055216 1E Rev Apr 2009

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

Issued April 2009