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## MEDICATION GUIDE

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**CREON® (krē 'ōn)**

392

**(pancrelipase)**

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**Delayed-Release Capsules**

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395 Read this Medication Guide before you or your child start taking CREON and each time you or your child get a  
396 prescription refilled. There may be new information. This information does not take the place of talking with your  
397 healthcare professional about your medical condition or your treatment.

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

399 ● CREON may increase your chance of having a rare bowel disorder called fibrosing colonopathy. This  
400 condition is serious and may require surgery. The risk of having this condition may be reduced by following  
401 the dosing instructions that your healthcare professional gave you. Call your healthcare professional right  
402 away if you have any unusual or severe stomach area (abdominal) pain.

403 ● **Take CREON exactly as prescribed. Do not take more or less CREON than directed by your**  
404 **healthcare professional.**

### 405 **What is CREON?**

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

409 CREON is safe and effective in children.

### 410 **What should I tell my healthcare professional before taking CREON?**

411 Tell your healthcare professional if you:

- 412 ● are allergic to pork (pig) products.
- 413 ● have a history of intestinal blockage or a condition called fibrosing colonopathy.
- 414 ● have gout, kidney disease, or a condition called high blood uric acid (hyperuricemia).
- 415 ● have trouble swallowing capsules.
- 416 ● are pregnant or planning to become pregnant. It is not known if CREON will harm your unborn baby.
- 417 ● are breast-feeding or plan to breast-feed. It is not known if CREON passes into your breast milk. **Tell your**  
418 **healthcare professional about all the medicines you take**, including prescription and nonprescription  
419 medicines, vitamins, and dietary or herbal supplements.

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

### 422 **How should I take CREON?**

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

#### 424 **Infants (up to 12 months)**

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

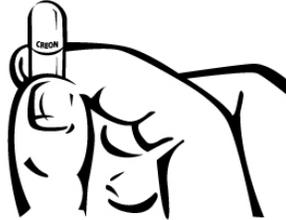
#### 429 **Children and Adults**

- 430 ● Always take CREON during a meal or a snack and follow it with sufficient fluid.

- 431 ● If you forget to take CREON, call your healthcare professional or wait until your next meal and take your  
 432 usual number of capsules. **Do not make up for missed doses.** Take your next dose at the usual time.
- 433 ● If you or your child takes more CREON than directed, call your healthcare professional right away.
- 434 ● Swallow CREON whole. Do not crush or chew the contents of the capsules.

435 If you have trouble swallowing capsules, you can add the contents of an open capsule directly onto your food.  
 436 To do so, carefully open the capsules and sprinkle the contents on a small amount of applesauce at room temperature  
 437 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.



438 **What are the possible side effects of CREON?**

439 **CREON may cause serious side effects, including:**

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

446 The most common side effects include:

- 447 ● gassiness (flatulence)
- 448 ● stomach area (abdominal) pain
- 449 ● headache
- 450 ● dizziness

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

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

455 **How should I store CREON?**

- 456 ● Store CREON at room temperature (up to 25°C or 77°F) for up to 12 weeks after the bottle is opened.

457 ● If you store CREON at temperatures greater than room temperature (up to 40°C or 104°F), throw away after  
458 30 days.

459 ● Store CREON in the container you were given by the pharmacy.

460 ● Keep the bottle closed tightly.

461 ● Protect the bottle from moisture.

462 ● **Keep CREON and all medicines out of reach of children.**

#### 463 **General information about the safe and effective use of CREON**

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

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

#### 471 **What are the ingredients in CREON?**

472 **Active Ingredient:** pancrelipase

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

#### 477 **Additional information about pancreatic enzymes**

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

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

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

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

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

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