

Creon pancreatic powder granules 5,000, 10,000, 25,000 unit enteric-coated granules

What is Creon?

- Creon contains a mixture of substances that help break down food in the body (known as enzymes), called pancreatic powder.
- Pancreatic powder is also called pancreatin. It aids in digestion.
- The enzymes are derived from porcine pancreatic glands.
- Creon capsules contain small beads that slowly release the pancreatic powder in your intestine (mini-microspheres with a coating that protects against stomach acid and disappears only after the stomach, when it reaches the intestine).
- Creon granules 5000 are intended for patients who cannot swallow capsules. It is used when patients require a low dose of pancreatin.

What is Creon used for?

This medicine is used in the treatment of "exocrine pancreatic insufficiency." In this condition, the pancreas does not produce enough digestive enzymes to digest food. This condition often occurs in people with the following diseases:

- Cystic fibrosis (a rare genetic disorder)
- Chronic pancreatitis (persistent inflammation of the pancreas)
- Partial or complete removal of the pancreas (partial or total pancreatectomy)
- Pancreatic cancer
- Creon can be used by children, adolescents, and adults.

How do you use this medicine?

Treatment with this medicine improves the symptoms of exocrine pancreatic insufficiency, including stool composition (fatty stools), abdominal pain, flatulence, and frequency of bowel movements (diarrhea or constipation), regardless of the underlying disease.

How does this medicine work?

The enzymes in this medicine work by digesting the food that passes through the intestines. You should take this medicine during or immediately after a meal or snack. This ensures that the enzymes mix well with the food.

When should you not use this medicine or take extra precautions?

When should you not use this medicine?

- You are allergic to any of the substances in this medicine.
- When should you take extra precautions with this medicine?
- Contact your doctor or pharmacist before using this medicine.

Patients with cystic fibrosis:

A rare intestinal condition called "colon stricture," where the intestines become narrowed, has been reported in patients with cystic fibrosis who use a high dose of pancreatic powder.

If you have cystic fibrosis and are taking more than 10,000 units of lipase per kilogram of body weight per day and experience unusual abdominal symptoms or changes in your abdominal symptoms, you should immediately contact your doctor.

The dosage in lipase units is explained in "**How do you use this medicine?**"

Severe allergic reaction: If a severe allergic reaction occurs, stop the treatment and contact your doctor. An allergic reaction may include itching, hives, or rash. Very rarely, an allergic reaction may include a feeling of warmth, dizziness, fainting, and difficulty breathing; these are symptoms of a severe, potentially life-threatening condition called "anaphylactic shock." If this occurs, seek immediate medical help (e.g., from your doctor). Contact your doctor if you are allergic to porcine proteins before using this medicine.

Mouth irritation: Pain in the mouth, irritation (stomatitis), bleeding, and the formation of ulcers in the mouth can occur when chewing on the capsules and/or keeping them in the mouth for too long. Rinsing the mouth and drinking a glass of water can help alleviate the initial signs of mouth irritation. This medicine can only be sprinkled on certain types of food.

This medicine contains less than 1 mmol of sodium (23 mg) per capsule, which means it is essentially "sodium-free."

Are you taking any other medicines?

If you are taking other medicines in addition to Creon, have taken them recently, or plan to take them in the near future, please inform your doctor or pharmacist.

Pregnancy and breastfeeding:

Are you pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding? Please contact your doctor or pharmacist before using this medicine. Your doctor will decide if you can take this medicine during pregnancy. This medicine can be used while breastfeeding.

Driving and using machinery:

This medicine does not affect your ability to drive or use machinery.

How do you use this medicine?

Always use this medicine exactly as your doctor or pharmacist has instructed you. If you are unsure about the correct usage, contact your doctor or pharmacist.

Your dose is measured in "lipase units." Lipase is one of the enzymes in pancreatin. The different strengths of Creon capsules contain different amounts of lipase. Always follow the dosage advice given by your doctor. Your doctor will determine the dose that is suitable for you.

The dose depends on:

- the severity of your condition
- your body weight
- your diet
- the amount of fat in your stool

If you still experience greasy diarrhea or other gastrointestinal symptoms, discuss with your doctor whether the dose may need to be adjusted.

How much of this medicine should I take?

Patients with cystic fibrosis:

Children

The dose required for a child should be determined by a doctor using a dosage form with fewer lipase units (e.g., 10,000 or 5,000 units).

- The usual starting dose for children under 4 years old is 1,000 lipase units per kilogram of body weight per meal.
- The usual starting dose for children older than 4 years old is 500 lipase units per kilogram of body weight per meal.

Adolescents and adults

The weight-based dosage for adolescents and adults should start with 500 lipase units per kilogram of body weight per meal.

For all age groups:

Your dose should not exceed 2,500 lipase units per kilogram of body weight per meal, or 10,000 lipase units per kilogram of body weight per day, or 4,000 lipase units per gram of fat intake.

For patients with other pancreatic problems:

Adolescents and adults

The usual dose for a meal ranges from 25,000 to 80,000 lipase units.

The usual dose for a snack is half the dose to be taken for a meal.

When should I use this medicine?

Always take this medicine during or immediately after a meal or snack. This ensures that the enzymes are properly mixed with the food and can digest the food as it passes through the digestive system.

How should I use this medicine?

- This medicine should always be taken during a meal or with a snack.
- For Creon granules 5,000: Always use the measuring spoon provided with the container of Creon granules 5,000. One measuring spoon contains 5,000 lipase units.
- Swallow the capsules whole, with an adequate amount of water or juice.
- Do not chew or crush the capsules or granules as this can cause irritation in the mouth and alter the effectiveness of this medicine in your body.

If it is difficult to swallow the capsules, the capsule can be carefully opened. The small granules can be added to a small amount of soft, acidic food or mixed with an acidic liquid. Acidic soft foods can be, for example, applesauce or yogurt. Acidic liquids can be apple, orange, or pineapple juice.

- Do not mix the granules with water, milk or flavored milk, breast milk or formula, or with hot food. Swallow the mixture immediately without grinding or chewing and then drink some water or juice.
- Mixing with non-acidic food or non-acidic liquid and crushing or chewing the microgranules can cause irritation in the mouth or alter the effectiveness of this medicine in the body.
- Do not keep the Creon capsules or granules (the mini-microgranules) in your mouth; make sure the medication and food mixture is completely swallowed and no granules are left in your mouth.
- The mixture should not be stored.

Have you used too much of this medicine?

Drink plenty of water if you have used too much of this medicine, and always contact your doctor or pharmacist.

Very high doses of pancreatic powder sometimes lead to excessive uric acid in the urine (hyperuricosuria) or in the blood (hyperuricemia).

Did you forget to use this medicine?

If you missed a dose, take the next dose at the usual time during your next meal. Do not take a double dose to make up for a missed dose.

If you stop using this medicine

Do not stop using this medicine without consulting your doctor. Many patients will need to use this medicine for the rest of their lives.

Do you have any other questions about using this medicine? Contact your doctor or pharmacist.

Possible side effects

Like any medicine, this medicine can have side effects. Not everyone experiences them. The following side effects may occur with the use of this medicine. The most important serious side effects seen with pancreatic enzyme replacement therapy are "anaphylactic shock" and stricture formation in the colon. These two side effects occurred in a very small number of users, but the exact frequency cannot be estimated. Anaphylactic shock is a serious, potentially life-threatening allergic reaction that can develop very quickly. If you notice any of the following symptoms, seek medical help immediately:

- Itching, hives, rash

- Swollen face, eyes, lips, hands, or feet
- Light-headedness or fainting
- Breathing difficulties or swallowing difficulties
- Palpitations
- Dizziness, fainting (collapse), or unconsciousness.

Repeated high doses in pancreatic enzyme replacement treatments can also cause scarring or thickening of the intestinal wall. This can lead to intestinal obstruction, a condition called colon stricture. If you experience severe abdominal pain, constipation, nausea, or vomiting, immediately contact your doctor.

Very common (affects more than 1 in 10 patients): Abdominal pain.

Common (affects less than 1 in 10 patients): Nausea; Vomiting; Constipation; Abdominal bloating; Diarrhea.

These side effects can also be caused by the condition for which you are using this medicine.

Rare (affects less than 1 in 100 patients): Rash.

Reporting side effects

If you experience any side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly to the Dutch Pharmacovigilance Centre Lareb, website www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

How to store this medicine?

Keep out of sight and reach of children.

Do not use this medicine after the expiry date stated on the label and the box after EXP. The expiry date refers to the last day of the specified month. Store below 25°C.

After opening: Creon granules 5,000: Store below 25°C and use within 3 months. Keep the bottle tightly closed to protect it from moisture.

Creon 10,000, 25,000: Store below 25°C and use within 6 months.

Keep the bottle tightly closed to protect it from moisture.

Do not dispose of medicines in wastewater or household waste.

Ask your pharmacist how to dispose of medicines that are no longer needed. When you dispose of medicines correctly, they are appropriately destroyed and do not harm the environment.