

CREON® Micro

Pancreatic Extract Enteric-Coated Granules

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about Creon Micro. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

Please read this leaflet before you start taking Creon Micro.

If you are helping someone else to take Creon Micro, please read this leaflet before you give the first dose.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Creon Micro against the benefits expected for you.

If you have any concerns about taking Creon Micro, ask your doctor or pharmacist.

Your doctor and pharmacist have more information.

Keep this leaflet with your Creon Micro.

You may need to read it again.

What Creon Micro is used for

Creon Micro is a pancreatic enzyme supplement used in a condition called pancreatic exocrine insufficiency where the body does not make enough enzymes to digest food. This condition appears in a number of different patients including those with cystic fibrosis, chronic pancreatitis, or patients who have had upper gastrointestinal surgery. People with a deficiency of pancreatic enzymes often suffer with symptoms of diarrhoea, steatorrhoea (foul fatty

stools which float in the toilet), bloating and weight loss. These symptoms appear because the body is unable to digest food normally.

When this happens your body's ability to absorb important nutrients from food is impaired and leads to malnutrition. If left untreated, these symptoms can affect your quality of life and a poor nutritional status could have long term health implications. The supplementation of pancreatic enzymes using Creon helps restore the normal digestive action in your body to relieve abdominal symptoms and improve nutritional status.

The enzymes are extracted from pancreas of pigs.

Creon Micro is approved for the uses listed above. However, your doctor may prescribe this medicine for another use. If you would like more information, ask your doctor.

There is no evidence that Creon Micro is addictive.

Before you take Creon Micro

When you must not take it

Do not take Creon Micro if you are allergic to pork, other pig products or any of the ingredients listed at the end of this leaflet.

Do not take Creon Micro after the expiry date (EXP) printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take Creon Micro if the packaging is torn or shows signs of tampering.

Before you start to take it

You must tell your doctor if you are allergic to any other medicines or any foods, dyes or preservatives.

You must tell your doctor if you are pregnant, planning to become pregnant, are breast feeding or intend to breast feed.

Your doctor will discuss whether you should take this product.

If you have not told your doctor about any of the above, tell them before you take Creon Micro.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

You should avoid taking antacids, which are medicines that are used to treat heartburn and indigestion, at the same time as when taking Creon Micro. Antacids may affect how well Creon Micro work by breaking down the special coating used to protect the pancreatic enzymes. If it is necessary to take an antacid, then it should be taken at least one hour before you take your Creon Micro.

How to take Creon Micro

Follow all directions given to you by your doctor carefully.

These directions may differ from the information in this leaflet.

How much to take

Your doctor will tell you how much Creon Micro to take or give to your child. Do not increase the number of doses yourself without informing your doctor.

Your doctor has prescribed a dose of Creon for you or your child which is specifically tailored to the severity of the condition.

It is normally not necessary to restrict your diet of fat while you are taking Creon as your symptoms will usually be under control. In people with malnutrition, getting enough fat in the diet will help improve nutrition. If unsure, you should consult your doctor or dietitian regarding your diet whilst on Creon.

The maximum recommended dose of lipase in infants and children with cystic fibrosis is 10,000 units per kilogram body weight in 24 hours.

Patients who use more than 10,000 units per kilogram per day, will probably be monitored closely by their doctor.

When to take it

Take Creon Micro with every meal and snack.

How to take it

The small measuring scoop that is provided with the bottle is designed to contain a dose of 100 mg of granules. This amount provides 5,000 units of lipase.

Creon Micro can be added to small amounts of acidic soft food that do not require chewing such as apple juice or mashed bananas. The mixture of Creon Micro and soft food should be swallowed immediately without crushing or chewing, and followed with water or juice to ensure complete ingestion. Care should be taken to ensure that no drug is retained in the mouth.

In young infants, Creon Micro should be mixed with a small amount of

apple juice and given from a spoon directly before the feed. In young infants, granules should be taken with acidic liquids or soft foods (e.g. mixed with apple juice or apple puree), but without chewing, directly before the meal. When giving Creon Micro to young infants the apple juice should not be diluted.

When you are taking Creon Micro, it is important to make sure that you drink plenty of liquid every day.

If you forget to take it

Wait until your next meal or snack and take your usual number of doses.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering when to take your medicine, ask your pharmacist for hints.

If you take too much (overdose)

If you, or anybody else, have taken too many Creon Micro drink plenty of water and contact your doctor, pharmacist or the Poisons Information Centre (13 11 26), or go to the casualty department of the hospital nearest to you. Do this even if there are no signs of discomfort or poisoning.

While you are taking Creon Micro

Things you must do

Make sure you tell your doctor if you are still having problems with fatty stools or abdominal pain while you are taking Creon Micro.

Drink plenty of water every day when you are taking Creon Micro.

Follow your doctor's instructions carefully and do not stop taking Creon Micro unless told to do so by your doctor.

If you are about to start taking any new medicines, tell your doctor

and pharmacist that you are taking Creon Micro.

Things you must not do

Do not give Creon Micro to anyone else, even if they have the same condition as you.

Do not use this medicine for any purpose other than for the purpose it has been recommended for you.

Do not use more than the recommended amount.

Do not stop taking your medicine until your doctor tells you to do so.

Do not let yourself run out of medicine unless told to do so by your doctor.

Creon Micro has no influence on the ability to drive and use machinery.

Things that may help your condition

Diet should be considered as part of your overall management plan. Talk to your doctor for more information and advice.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Creon Micro.

Creon Micro helps most people whose bodies do not make enough enzymes to digest their food, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- **stomach or bowel problems, including:**

- diarrhoea
 - constipation
 - abnormal stools
 - abdominal discomfort
 - nausea
- skin reactions

Tell your doctor immediately if you have severe or prolonged abdominal pain.

If you take too much Creon Micro you may get irritation or inflammation in the anal region.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

The active ingredient in Creon Micro is an extract of pancreatic powder of porcine origin (pigs), therefore the presence of porcine parvovirus or other porcine viruses cannot be totally excluded. However, there is no evidence of transmission of these viruses to humans or of porcine pancreatic powder extracts causing illness in humans.

After taking Creon Micro

Storage

Keep the container tightly closed in order to protect from moisture.

Keep your Creon Micro in a cool dry place where the temperature stays below 25°C. Please note that in warmer climates it may be necessary to store Creon Micro in the refrigerator. After opening use within 3 months.

Do not store it, or any other medicine, in the bathroom or near a sink.

Do not leave it in the car or on a window sill on hot days.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Creon Micro or they passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Creon® Micro: Round, light brown enteric-coated granules in glass bottles. Each glass bottle contains 20 g of enteric-coated granules. Measuring scoop supplied.

Ingredients

Each dosing unit of 100 mg of Creon® Micro contains Pancreatic Extract 60.12 mg equivalent to not less than 5,000 Ph.Eur. units lipase, 3,600 Ph.Eur. units amylase and 200 Ph. Eur. units protease.

Inactive ingredients in Creon Micro are: macrogol 4000, hypromellose phthalate, cetyl alcohol, triethyl citrate, dimeticone 1000. One dosage unit is measured with a measuring scoop as dosing device.

Sponsor

Creon® Micro is manufactured in Germany for:

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