

CREON® 10,000 CREON® 25,000 *Pancreatin Capsules*



What is in this leaflet

This leaflet answers some common questions about Creon.

It does not contain all 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.

If you are helping someone else to take Creon, 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 against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Creon is used for

Creon is a pancreatic enzyme supplement used to treat conditions associated with pancreatic exocrine insufficiency, such as:

- cystic fibrosis
- chronic pancreatitis
- various upper gastrointestinal surgery

People with pancreatic exocrine insufficiency often suffer with symptoms of:

- abdominal pain
- diarrhoea

- steatorrhoea (foul fatty stools which float in the toilet)
- bloating
- 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.

Creon capsules contain digestive enzymes (amylase, lipase, protease) extracted from the pancreas of pigs.

The supplementation of pancreatic enzymes using Creon helps restore the normal digestive action in your body to relieve abdominal symptoms and improve nutritional status.

Creon 25,000 is available only with a doctor's prescription.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

There is no evidence that Creon capsules are addictive.

This medicine is not expected to affect your ability to drive a car or operate machinery.

Before you take Creon

When you must not take it

Do not take Creon if you have an allergy to:

- any medicine containing pancreatic enzymes
- pork or other pig products
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking Creon.

Taking other medicines

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while being treated with Creon.

How to take Creon

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how many capsules to take to suit your particular needs. Do not increase the number of capsules yourself without informing your doctor.

For children and adults with cystic fibrosis, your doctor will have determined a dose specific to your body weight and condition.

For adult patients starting Creon for the first time, the usual starting dose is 25,000 to 40,000 units of lipase with each meal and half this dose with snacks. Your doctor may need to make a number of adjustments before determining the right dose which suits you best. If needed, the dose can be increased up to 80,000 units of lipase with each meal.

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.

If the doctor advises you to increase the dosage, you should increase the number of capsules gradually (for example, by one at a time). A very rapid increase in dosage may lead to constipation. If you are unsure how to increase the dose, ask your doctor or pharmacist to explain it to you.

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.

How to take it

Swallow the capsules whole with a full glass of water or, if you prefer, open the capsules and mix the granules with soft food such as apple sauce, yoghurt or fruit juice.

If you mix the granules with food, it is important to swallow the mixture straight away, without chewing.

Neither the capsules nor the granules inside should be crushed or chewed as they have a special coating to stop them dissolving until they have gone through the stomach and into the intestines where they work.

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

When to take it

Take Creon with every meal and snack.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

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

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

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

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

If you take too much (overdose)

If you, or anybody else, have taken too many Creon capsules, drink plenty of water and contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital immediately. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Extremely high doses of pancreatin have been associated with excessive amounts of uric acid in the urine and the blood. If you take too much Creon you may get irritation or inflammation in the anal region.

While you are taking Creon

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.

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

Follow your doctor's instructions carefully and do not stop taking Creon 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.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this product.

If you become pregnant while taking this product, tell your doctor immediately.

Things you must not do

Do not take Creon to treat any other complaints unless your doctor tells you to.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

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

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

Things that would be helpful for your condition

Diet should be considered as part of your overall management plan. Talk to your doctor or dietician 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 capsules.

Creon capsules help 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.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

- stomach or bowel problems, including:
 - diarrhoea
 - constipation
 - abnormal stools
 - abdominal discomfort
 - nausea
 - vomiting
- skin reactions

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

Several children with cystic fibrosis taking high doses of pancreatic enzyme supplements have suffered from narrowing of the bowel and required an operation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

In rare cases, people taking very high doses may develop high levels of uric acid in their blood and urine.

After taking Creon

Storage

Keep your capsules in the bottle until it is time to take them.

If you take the capsules out of the bottle they may not keep well.

Keep your Creon capsules 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 capsules in the refrigerator.

Use within six months after opening.

Do not store Creon or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Creon 10,000 is a dark brown/colourless capsule containing small brownish coloured pellets (minimicrospheres) that have a special coating. Available in bottles of 100 capsules.

Creon 25,000 is a Swedish orange/colourless capsule containing small brownish coloured pellets (minimicrospheres) that have a special coating. Available in bottles of 100 capsules.

Ingredients

Each Creon 10,000 capsule contains 150 mg of pancreatin equivalent to not less than lipase 10,000 Ph. Eur. units, amylase 8,000 Ph. Eur. units and protease 600 Ph. Eur. units as the active ingredient.

Creon 10,000 capsules also contains inactive ingredients:

- macrogol 4000
- hypromellose phthalate
- cetyl alcohol
- triethyl citrate
- dimethicone
- gelatin
- iron oxide (E172)
- titanium dioxide
- sodium lauryl sulfate

Each Creon 25,000 capsule contains 300 mg of pancreatin equivalent to not less than lipase 25,000 Ph. Eur. units, amylase 18,000 Ph. Eur. units and protease 1,000 Ph. Eur. units as the active ingredient.

Inactive ingredients in Creon 25,000 capsules are:

- macrogol 4000
- hypromellose phthalate
- cetyl alcohol
- triethyl citrate
- dimethicone

- gelatin
- iron oxide (E172)
- titanium dioxide
- sodium lauryl sulfate

Gelatin raw material may contain sulfur dioxide residue.

This medicine does not contain lactose, or gluten.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

Date of Information

23 November 2017
(Based on datasheet dated 23
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