

CREON® Capsules

Pancreatic Extract Enteric-Coated Minimicrospheres

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about Creon 10,000, Creon 25,000, Creon 35,000 and Creon 40,000 capsules. 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 capsules.

If you are helping someone else to take Creon capsules, 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 capsules against the benefits expected for you.

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

Your doctor and pharmacist have more information.

Keep this leaflet with your Creon capsules.

You may need to read it again.

What Creon Capsules are used for

Creon 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 capsules are 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.

Creon 25,000, Creon 35,000 and Creon 40,000 cannot be obtained without a doctor's prescription.

There is no evidence that Creon capsules are addictive.

Before you take Creon Capsules

When you must not take it

Do not take Creon capsules 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 capsules 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 capsules if the packaging is torn or shows signs of tampering, or if the capsules do not look quite right.

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 these products.

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

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, when taking Creon capsules. Antacids may affect how well Creon capsules 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 capsules.

How to take Creon Capsules

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 many capsules to take to suit your particular needs. Do not increase the number of capsules yourself without informing your doctor.

For children and adolescents with cystic fibrosis, your doctor will have determined a dose specific to the patient's 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.

When to take it

Take Creon capsules with every meal and snack.

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.

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 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.

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.

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 capsules, 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 Capsules

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 capsules.

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

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

Things you must not do

Do not give Creon capsules 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 has no influence on the ability to drive and use machines.

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 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.

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.

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

Tell your doctor if you notice any other symptom while you are taking Creon capsules.

In rare cases, people taking very high doses have had a tendency to develop high levels of uric acid in their blood and urine.

If you take too much Creon 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 capsules 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 Capsules

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. After opening use within 6 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-a-half metres above the ground is a good place to store medicines.

Disposal

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

Product description

What it looks like

CREON 10,000 is a dark brown/colourless capsule containing small brownish coloured granules (minimicrospheres) that

have a special coating. Available in bottles of 100 capsules.

CREON 25,000 is a light brown/colourless capsule containing small brownish coloured granules (minimicrospheres) that have a special coating. Available in bottles of 100 capsules.

CREON 35,000 is a red brown/colourless capsule containing small brownish coloured granules (minimicrospheres) that have a special coating. Available in bottles of 100 capsules.

CREON 40,000 is an opaque brown/colourless-transparent capsule containing brownish minimicrospheres in bottles of 100 capsules.

Ingredients

Each CREON 10,000 capsule contains Pancreatin Extract 150 mg equivalent to not less than lipase 10,000 Ph.Eur. units, amylase 8,000 Ph.Eur. units and protease 600 Ph.Eur. units.

Inactive ingredients in CREON 10,000 capsules are: macrogol 4000, hypromellose phthalate, cetyl alcohol, triethyl citrate, dimeticone 1000, gelatin, iron oxide red, iron oxide black, iron oxide yellow, titanium dioxide and sodium lauryl sulfate.

Each CREON 25,000 capsule contains Pancreatic Extract 300mg equivalent to not less than lipase 25,000 Ph.Eur. units, amylase 18,000 Ph.Eur. units and protease 1,000 Ph. Eur. units.

Inactive ingredients in CREON 25,000 capsules are: macrogol 4000, hypromellose phthalate, cetyl alcohol, triethyl citrate, dimeticone 1000, gelatin, iron oxide red, iron oxide yellow, titanium dioxide and sodium lauryl sulfate.

Each CREON 35,000 capsule contains Pancreatic Extract 420 mg equivalent to not less than lipase 35,000 Ph.Eur. units, amylase

25,200 Ph.Eur. units and protease
1,400 Ph. Eur. units.

Inactive ingredients in CREON
35,000 capsules are: macrogol
4000, hypromellose phthalate, cetyl
alcohol, triethyl citrate, dimeticone
1000, gelatin, iron oxide red, iron
oxide black, iron oxide yellow,
titanium dioxide and sodium lauryl
sulfate.

Each CREON 40,000 capsule
contains Pancreatic Extract 400mg
equivalent to not less than lipase
40,000 Ph.Eur. units, amylase
25,000 Ph.Eur. units and protease
1,600 Ph. Eur. units.

Inactive ingredients in CREON
40,000 capsules are: macrogol
4000, hypromellose phthalate, cetyl
alcohol, triethyl citrate, dimeticone
1000, gelatin, iron oxide, titanium
dioxide and sodium lauryl sulfate.

CREON also contains sulfites.

Sponsor

CREON is manufactured in
Germany for:

Mylan Health Pty Ltd
Level 1, 30 The Bond
30-34 Hickson Road
Millers Point, NSW 2000
Australia
www.mylan.com.au
Phone: 1800 314 527

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CREON 35,000: AUST R 313833

CREON 40,000: AUST R 158451