

PACKAGE LEAFLET: INFORMATION FOR THE USER

Creon 10000 Gastro-resistant Capsules

Creon 25000 Gastro-resistant Capsules

pancreatin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Creon is and what it is used for
2. What you need to know before you take Creon
3. How to take Creon
4. Possible side effects
5. How to store Creon
6. Contents of the pack and other information

1. WHAT CREON IS AND WHAT IT IS USED FOR

What Creon is

- Creon contains an enzyme mixture called “pancreatin”.
- Pancreatin helps you digest food. The enzymes are taken from pig pancreas glands.
- Creon gastro-resistant capsules contain small pellets which slowly release the pancreatin in your gut (gastro-resistant pellets, called Minimicrospheres™).

What Creon is used for

- Creon is used by children and adults with “pancreatic exocrine insufficiency”. This is when their pancreas gland does not make enough enzymes to digest food.

How Creon works

The enzymes in Creon work by digesting food as it passes through the gut. You should take Creon during or immediately after a meal or a snack. This will allow the enzymes to mix thoroughly with the food.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CREON

Do not take Creon if:

- you are allergic (hypersensitive) to pig pancreatin or to any of the other ingredients of Creon (listed in section 6).

If you are not sure, talk to your doctor or pharmacist before taking Creon.

Warnings and Precautions

A rare bowel condition called “fibrosing colonopathy”, where your gut is narrowed, has been reported in patients with cystic fibrosis taking high dose pancreatin products. However, this is not known to have happened during studies in patients taking Creon.

However, if you have cystic fibrosis and take in excess of 10000 lipase units per kilogram per day and have unusual abdominal symptoms or changes in abdominal symptoms **tell your doctor.**

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Pregnancy, breast-feeding and fertility

- Talk to your doctor before taking this medicine if you are pregnant or might become pregnant. Your doctor will decide if you should take Creon and at which dose. Creon can be used while breast-feeding.

Driving and using machines

It is unlikely that Creon will affect your ability to drive or operate tools or machines.

3. HOW TO TAKE CREON

Always take Creon exactly as your doctor has told you. You should check with your doctor if you are not sure.

How much Creon to take

- Your dose is measured in ‘lipase units’. Lipase is one of the enzymes in pancreatin. Different strengths of Creon contain different amounts of lipase.
- Always follow your doctor’s advice on how much Creon to take.
- Your doctor will adjust your dose to suit you. It will depend on:
 - your illness
 - your weight
 - your diet
 - how much fat is in your stools.
- If you still have fatty stools or other stomach or gut problems (gastrointestinal symptoms), talk to your doctor as your dose may need to be adjusted.
- If your doctor advises you to increase the number of capsules you take, you should do so slowly.

When to take Creon

Always take Creon during or immediately after a meal or a snack. This will allow the enzymes to mix thoroughly with the food and digest it as it passes through the gut.

How to take Creon

- Swallow the capsules whole.

- Do not crush or chew the capsules.
- If it is difficult to swallow the capsules, open them carefully and add the pellets to a small amount of soft acidic food. This could for example be applesauce. Swallow the mixture immediately, without crushing or chewing and drink some water or juice, e.g. apple, orange or pineapple juice. Or, you can also just take the pellets with liquid.
- Care should be taken that no product is retained in the mouth.
- As a general rule, drink plenty of liquid every day.

How long to take Creon for

Take Creon until your doctor tells you to stop. Many patients will need to take Creon for the rest of their lives.

If you take more Creon than you should

If you take more Creon than you should, drink plenty of water and talk to a doctor or pharmacist.

Very high doses of pancreatin have sometimes caused too much uric acid in the urine (hyperuricosuria) and in the blood (hyperuricaemia).

If you forget to take Creon

If you forget a dose, take your next dose at the usual time, with your next meal. Do not try to make up for the dose that you have missed.

If you stop taking Creon

Do not stop taking Creon without first talking to your doctor.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Creon can cause side effects, although not everybody gets them. If you experience any of the following serious side effects, stop taking this medication and seek urgent medical attention immediately:

The most important serious side effects seen with pancreatic enzyme replacement medicines are ‘anaphylactic shock’ and fibrosing colonopathy. These two side effects have occurred in a very small number of people, but their exact frequency is unknown.

Anaphylactic shock is a severe, potentially life-threatening allergic reaction that can develop rapidly. If you notice any of the following seek urgent medical attention straightaway:

- itching, hives or rash
- swollen face, eyes, lips, hands or feet
- feeling lightheaded or faint
- trouble breathing or swallowing
- palpitations
- dizziness, collapse or unconsciousness

Repeated high doses of pancreatic enzyme replacement medicines can also cause scarring or thickening of the bowel wall that can lead to blockage of the intestines, a condition

called fibrosing colonopathy. If you have severe stomach pain, trouble passing stools (constipation), nausea or vomiting, tell your doctor straightaway.

Other possible side effects include:

Very common side effects (may affect more than 1 in 10 people)

- pain in your stomach (abdomen).

Common side effects (may affect up to 1 in 10 people)

- feeling sick (nausea)
- being sick (vomiting)
- constipation
- bloating (abdominal distention)
- diarrhoea.

These may be due to the condition you are taking Creon for. During studies, the number of patients taking Creon who had pain in their stomach or diarrhoea was similar or lower than in patients not taking Creon.

Uncommon side effects (may affect up to 1 in 100 people)

- rash.

Not known (frequency cannot be estimated from the available data)

- severe itching (pruritus)
- hives (urticaria).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

In Ireland: HPRA Pharmacovigilance, Website: www.hpra.ie

In Malta: ADR Reporting, Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CREON

- Keep out of the sight and reach of children.
- Do not store above 25°C. Keep container tightly closed in order to protect from moisture.
- After first opening do not store above 25°C and use within 6 months.
- Do not take Creon after the expiry date, which is stated on the pack. The expiry date refers to the last day of that month.

- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Creon contains

- The active ingredient in Creon is pancreatin.
- Each Creon 10000 gastro-resistant capsule contains 150 mg pancreatin corresponding to (Ph.Eur. units):
 - Amylase 8000
 - Lipase 10000
 - Protease 600
- Each Creon 25000 gastro-resistant capsule contains 300 mg pancreatin corresponding to (Ph.Eur. units):
 - Amylase 18000
 - Lipase 25000
 - Protease 1000
- The other ingredients are:
 - Granules: macrogol 4000, hypromellose phthalate, dimethicone, triethyl citrate, cetyl alcohol
 - Capsule: iron oxides (E 172), titanium dioxide (E 171), sodium lauryl sulphate, gelatin

What Creon looks like and the contents of the pack

- The Creon 10000 gastro-resistant capsules are brown and transparent. They contain gastro-resistant pellets (Minimicrospheres™).
- The Creon 25000 gastro-resistant capsules are orange and transparent. They contain gastro-resistant pellets (Minimicrospheres™).
- Creon is available in bottles with 50 capsules, 100 capsules, 250 capsules, 300 capsules.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan IRE Healthcare Limited,
Unit 35/36,
Grange Parade,
Baldoyle Industrial Estate,
Dublin 13.

Manufacturer

Abbott Laboratories GmbH,
31535 Neustadt a. Rbge,
Germany.

This leaflet was last revised in February 2021

More information about cystic fibrosis and pancreatitis

You can find out more about Cystic Fibrosis from the following organisation:

The Cystic Fibrosis Association of Ireland, CF House, 24 Lower Rathmines, Dublin 6.