

Patient Information Leaflet

Creon® 10000 capsules pancreatin

Important things you **SHOULD** know about Creon 10000

- Creon 10000 is a pancreatic enzyme supplement for people whose bodies do not make enough enzymes to digest their food.
- **Take** the number of capsules as prescribed by your doctor or dietician.
- **Take** Creon 10000 during or immediately after a meal or a snack and drink plenty of water.
- **Do not take** Creon 10000 if you are allergic to pork or any pig product.
- **If** you experience severe abdominal pain while taking Creon 10000, contact your doctor immediately.
- Most people do not have problems taking Creon 10000 but side effects can occur (see section 4).

Please read the rest of this leaflet carefully before you start taking these capsules. It includes other important information on the safe and effective use of this medicine that might be especially important for you

How to find the information you need

1. **About Creon 10000** What Creon 10000 is and how it works.
2. **Before you take Creon 10000**
Who can take Creon 10000?
Can you take Creon 10000 if you are pregnant or breast-feeding?
Driving or operating machinery.
3. **How to take Creon 10000**
How much Creon 10000 you should take.
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How you should take Creon 10000.
What to do if you take too much Creon 10000.
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4. **Possible side effects**
Abdominal symptoms (such as abdominal pain).
Side effects and what to do if you get them.
5. **How to store Creon 10000**
How and where to keep your capsules.
6. **Further information**
The ingredients in Creon 10000.
More information about cystic fibrosis and pancreatitis.

This medicine has been prescribed for you personally. Don't offer it to other people, even if their symptoms seem to be the same as yours.

1. **About Creon 10000**

What is Creon 10000

- Creon 10000 is a pancreatic enzyme supplement.
- Pancreatic enzyme supplements are used by people whose bodies do not make enough of their own enzymes to digest their food.
- Creon 10000 capsules contain a mixture of the natural enzymes which are used to digest food.
- The enzymes are taken from pig pancreas glands.

How does Creon 10000 work?

The enzymes in Creon 10000 work by digesting food as it passes through the gut. So, you must take Creon 10000 at the same time as eating a meal or a snack. This will allow the enzymes to mix thoroughly with the food.

2. Before you take Creon 10000

Do not take Creon 10000 if:

- You are allergic to pork, any pig product, or to any of the other ingredients (see section 6).

If the above applies to you do not take Creon 10000. Talk to your doctor or dietician again.

When you need to take special care with Creon

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.

If you have cystic fibrosis and take in excess of 10,000 lipase units per kilogram per day and have unusual abdominal symptoms or changes in abdominal symptoms **tell your doctor.**

Talk to your doctor if:

- you are pregnant or trying to get pregnant (Creon 10000 can be used while breast feeding)

Please tell your doctor dietician or pharmacist if you think that you should not take Creon 10000 for any other reason.

If you drive or use machines

It is unlikely that Creon 10000 will affect your ability to drive or operate tools or machines.

Sodium content

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

3. How to take Creon 10000

How much Creon 10000 to take

- **Always follow your doctor or dietician’s advice on how many capsules to take.**
- If your doctor advises you to increase the number of capsules you take, you should do so slowly. If you still have fatty stools or abdominal pain, talk to your doctor or dietician.

When to take Creon 10000

- Always take Creon 10000 during or immediately after eating a meal or a snack and drink plenty of water (see section 1).

How to take Creon 10000

- Swallow the capsules whole or
- Open the capsules and mix the granules (without crushing) with acidic liquid (e.g. apple, orange or pineapple juice) or soft food (e.g. apple sauce or yoghurt). Swallow the mixture straight away, without chewing.
- Drink plenty of liquid every day.
- Mixing with non-acidic food or liquid, crushing or chewing of the pellets may cause irritation in your mouth or change the way Creon works in your body.
- Do not hold Creon capsules or its content in your mouth.
- Do not store the mixture.

How long to take Creon 10000 for

You should take your medicine until your doctor tells you to stop. Many patients will need to take pancreatic enzyme supplements for the rest of their lives.

If you take too much Creon 10000

If you take too much Creon 10000 you should drink plenty of water and see your doctor immediately.

If you forget a dose

If you forget to take your medicine, wait until your next meal and take your usual number of capsules. Do not try to make up for the number of capsules that you have missed. **Just take your next dose at the usual time.**

4. Possible side effects

Like all medicines, Creon 10000 can cause side effects (unwanted effects or reactions), but not everyone gets them.

If you have severe or long-lasting abdominal pain, contact your doctor immediately.

If you notice any **unusual abdominal symptoms** while taking Creon 10000 – contact your doctor.

Very common side effects (affect more than 1 in 10 patients):

- stomach pains

Common side effects (affect 1-10 patients out of 100):

- diarrhoea
- constipation
- feeling or being sick
- bloating

Uncommon side effects (affect 1-10 patients out of 1000):

- Skin reactions, such as a rash.

During use, some patients have also experienced the following, the frequency of which is unknown:

- itching with or without a rash
- allergic reactions (which may be severe)
- severe or long-lasting abdominal pain (Fibrosing colonopathy).

At extremely high doses, some patients have had high levels of uric acid in their blood and urine.

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 listed below.

In the UK:

The Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard

or search for MHRA Yellow Card in the Google Play or Apple App Store

In Malta:

Website: www.medicinesauthority.gov.mt

e-mail: post-licensing.medicinesauthority@gov.mt

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

5. How to store Creon 10000

How and where to keep your capsules

Keep this medicine out of the sight and reach of children.

Do not store above 25°C and keep in the original container. After opening do not store above 25 °C and use within 6 months. Keep the container tightly closed. The enzymes in Creon 10000 are natural products and their ability to digest food decreases over time. If the container is left in warm conditions (e.g. the glove compartment of a car), the digestive activity decreases faster.

Do not take Creon 10000 capsules after the expiry date on the bottle.
Return all unused medicine to your pharmacist.

6. Further information

The ingredients in Creon 10000

The active ingredient in Creon 10000 is pancreatin.

Each capsule contains enteric coated brownish-coloured granules (minimicrospheres) containing pancreatin 150 mg, equivalent to:

List of Enzymes: (PhEur units per capsule)

Lipase 10,000

Amylase 8,000

Protease 600

The granules are coated with a mixture of the following ingredients: macrogol 4000, hypromellose phthalate, dimeticone, triethyl citrate and cetyl alcohol.

The capsules contain: gelatin, iron oxides (E172), titanium dioxide (E171) and sodium lauryl sulfate.

Creon 10000 is available in 100, 250 or 300 capsule packs. Not all pack sizes may be marketed.

The Marketing Authorisation Holder is:

Mylan Products Ltd,
20 Station Close, Potters Bar,
Herts, EN6 1TL, UK.

The Manufacturer is:

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

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