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Patient Information Leaflet

Creon® 25000 Capsules

Pancreatin

Important things you SHOULD know about Creon 25000

- Creon 25000 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 25000 with a meal or a snack and drink plenty of water.
- **Do not take** Creon 25000 if you are allergic to pork or any pig product.
- If you experience **severe abdominal pain** while taking Creon 25000, contact your doctor immediately.
- Most people do not have problems taking Creon 25000 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 25000**
   What Creon 25000 is and how it works.
2. **Before you take Creon 25000**
   Who can take Creon 25000?
   Can you take Creon 25000 if you are pregnant or breast-feeding?
   Driving or operating machinery.
3. **How to take Creon 25000**
   How much Creon 25000 you should take.
   When you should take Creon 25000.
   How you should take Creon 25000.
   What to do if you take too much Creon 25000.
   What to do if you forget a dose.
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 25000**
   How and where to keep your capsules.
6. **Further Information**
   The ingredients in Creon 25000.
   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 25000

What is Creon 25000

- Creon 25000 is a high strength 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 25000 granules contain a mixture of the natural enzymes which are used to digest food.
- The enzymes are taken from pig pancreas glands.

How does Creon 25000 work?

The enzymes in Creon 25000 work by digesting food as it passes through the gut. So you must take Creon 25000 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 25000

Do not take Creon 25000 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 25000. 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**.

Additional information about pancreatic enzymes

The pancreas glands used to make Creon and other pancreatic enzyme products come from pigs used for food. These pigs may carry viruses. When Creon is made several steps are taken to reduce the risk of viruses being spread, including their destruction and testing for specific viruses. The risk of infections caused by these or other unknown or novel viruses cannot be totally ruled out. However, there have not been any cases reported where infection of patients has occurred.

Talk to your doctor, if:

- you are pregnant or trying to get pregnant (Creon 25000 can be used while breast-feeding)

Please tell your doctor, dietician or pharmacist if you think that you should not take Creon 25000 for any other reason.

If you drive or use machines

It is unlikely that Creon 25000 will affect your ability to drive or operate tools or machines.

3. How to take Creon 25000

How much Creon 25000 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 25000

- Always take Creon 25000 at the same time as eating a meal or a snack and drink plenty of water (see section 1).

How to take Creon 25000

- 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.

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How long to take Creon 25000 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 25000

If you take too much Creon 25000, 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 25000 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 25000 – 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.

If you notice any unwanted effect (even one not mentioned in this leaflet), or if you feel unwell while taking Creon 25000: **Tell your doctor.**

5. How to store Creon 25000

How and where to keep your capsules

Keep all medicines out of the reach and sight of children – preferably locked in a cupboard or medicine cabinet.

Do not store above 30°C and keep in the original container. The enzymes in Creon 25000 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 25000 capsules after the expiry date on the bottle. Return all unused medicine to your pharmacist.

6. Further information

The ingredients in Creon 25000

The active ingredient in Creon 25000 is pancreatin.

Each capsule contains enteric coated brownish-coloured granules (minimicrospheres) containing pancreatin 300 mg, equivalent to:

List of Enzymes: (PhEur units per capsule)

Lipase	25,000
Amylase	18,000
Protease	1,000

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 sulphate.

Creon 25000 is available in 100 capsule packs.

The Marketing Authorisation Holder is:
Abbott Healthcare Products Limited,
Southampton, SO18 3JD, UK.

The Manufacturer is:
Abbott Laboratories GmbH,
31535 Neustadt a. Rbge, Germany.

More information about cystic fibrosis and pancreatitis

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

The CF Trust
11 London Road, Bromley BR1 1BY.

You can find out more about Pancreatitis from the following organisation:

Pancreatitis Supporters Network
PO Box 8938, Birmingham B13 9FW.

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This leaflet was last revised in December 2012.

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