PATIENT INFORMATION LEAFLET

Creon® 10000 Capsules

(pancreatin)

The name of your medicine is Creon 10000 Capsules but will be referred to as Creon 10000 or Creon throughout this leaflet.

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT CREON IS AND WHAT IT IS USED FOR

- 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 after a meal or a snack. This will allow the enzymes to mix thoroughly with the food.

2. 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.

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. 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 10 000 lipase units per kilogram per day and have unusual abdominal symptoms or changes in abdominal symptoms **tell your doctor.**

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

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 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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Creon can cause side effects, although not everybody gets them. The following side effects were seen during studies in patients taking Creon. These side effects may happen with this medicine:

Very Common (affects more than 1 in 10 people)
- pain in your stomach (abdomen).

Common (affects less than 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 (affects less than 1 in 100 people)
- rash.

Severe itching (pruritus) and hives (urticaria) have also been reported.
Other serious allergic (hypersensitive) reactions may be caused by Creon. These can include trouble with breathing or swollen lips.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CREON

How and where to keep your capsules

Keep out of the reach and sight of children.

Do not store above 25°C and keep in the original container.

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 which is stated on the bottle and carton. The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist for safe disposal.

6. FURTHER INFORMATION

The ingredients in Creon 10000

The active ingredient in Creon 10000 is pancreatin.

The capsules are size 2 hard gelatin capsules with brown caps and colourless bodies filled with gastro-resistant brown granules.
Each capsule contains 150mg pancreatin equivalent to:

Ph. Eur. Units per Capsule
Lipase 10,000
Amylase 8,000
Protease 600

The granules (mini-microspheres) are coated with a mixture of other ingredients: macrogol 4000, cetyl alcohol, triethyl citrate, hypromellose phthalate and dimeticone.

The capsule shell is made of gelatin and sodium lauryl sulphate with red, yellow and black iron oxides (E172) and titanium dioxide (E171)

Creon 10,000 is available in HDPE container with polypropylene closure: containing 50 or 100 capsules.

Manufactured by: Abbott Products GmbH, Justus von liebig strasse 33, 31535 Neustadt, Germany.

Abbott Products GmbH, Neustadt, Germany.

Procured from within the EU and repackaged by PPA Holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Creon® 10000 Capsules
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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.

You can find out more about pancreatitis from the following organisation:
Pancreatitis Supporters Network
PO Box 8938, Birmingham, B13 9FW, UK.

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