

PACKAGE LEAFLET: INFORMATION FOR THE USER

Creon® 25000 Gastro-resistant Capsules (pancreatin)

Your medicine is available using the above name, but will be referred to as '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.

In this leaflet:

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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 contains 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

- Keep out of the sight and reach of children.
- Do not store above 25°C. Store in the original container.
- Do not take Creon after the expiry date, which is stated on the pack (Exp). The expiry date refers to the last day of that month.
- If your doctor decides to stop the treatment, return any leftover medicine to the pharmacist. Only keep it if your doctor tells you to.
- If your medicine appears to be discoloured or show any other signs of deterioration, please return to your pharmacist who will advise you further.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. 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 capsule contains 300mg pancreatin equivalent to:

- Lipase 25,000 Ph. Eur. units
- Amylase 18,000 Ph. Eur. units
- Protease 1,000 Ph. Eur. Units

The other ingredients are:

Granules: macrogol 4000, hypromellose phthalate, cetyl alcohol, triethyl citrate and dimethicone

Capsule: gelatin, iron oxides (E172), titanium dioxide (E171) and sodium lauryl sulphate.

What Creon looks like and the contents of the pack

Creon are hard gelatin capsules with opaque orange caps and colourless transparent bodies filled with gastro-resistant brown granules.

Creon is available in packs containing 100 capsules.

Manufacturer

Manufactured by: Abbott Laboratories GmbH,
31535 Neustadt a. Rbge, Germany.

Procured from within the EU by the PPA holder: Imbat Ltd.,
Unit L2, North Ring Business Park, Santry, Dublin 9.

Repackaged by: Doncaster Pharmaceuticals Group Ltd.,
Kirk Sandall, Doncaster, South Yorkshire, DN3 1QR, UK.

Distributed by: Eurodrug Ltd., Santry, Dublin 9.

PPA No: 1151/65/2

For information in Ireland contact
BGP Products Ireland Ltd., 4051 Kingswood Drive,
Citywest Business Campus, Dublin 24.

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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