

(pancreatin)

Patient Information 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.

Your medicine is called Creon 25000 gastro-resistant capsules, but will be referred to as Creon throughout this leaflet.

In this leaflet:

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- 2 Before you take Creon
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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 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**.

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.

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.

Creon® 25000 gastro-resistant capsules

(pancreatin)

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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 sight and reach of children –

preferably locked in a cupboard or medicine cabinet.

Do not store above 25°C and keep in the original container. The enzymes in Creon 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 use Creon after the expiry date, which is stated on the label or carton after EXP. The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist: Medicines should not be disposed of via waterwaste or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help the environment.

6 Further Information

What Creon contains

The active ingredient in Creon is pancreatin.

Each capsule contains pancreatin 300mg, 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 sulfate.

What Creon looks like and the contents of the pack

Creon are Capsules with orange caps and colourless transparent bodies with brownish granules (microminispheeres).

Creon is available in a bottle containing 100 capsules in a overlabelled outer carton.

The manufacturer is:

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

Parallel Product Authorisation Holder:

LTT Pharma Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

Repackaged by:

Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

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Blind or partially sighted?

Is this leaflet hard to see or read?

Phone LTT Pharma Limited, Tel: +44 (0)1527 505414

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