

Package leaflet: Information for the patient

Creon 20 000 gastro-resistant capsules, hard Pancreas powder

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Creon is and what it is used for
2. What you need to know before you take Creon
3. How to take Creon
4. Possible side effects
5. How to store Creon
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1. What Creon is and what it is used for

What Creon is

- Creon contains an enzyme mixture called “pancreas powder”.
- Pancreas powder is also called pancreatin. It helps you digest food. The enzymes are taken from pig pancreas glands.
- Creon capsules contain small pellets which slowly release the pancreas powder in your gut (gastro-resistant pellets, called minimicrospheres).

What Creon is used for

Creon is used for the treatment of “pancreatic exocrine insufficiency”. This is when the pancreas gland does not make enough enzymes to digest food. It is for example often found in people who have:

- cystic fibrosis, a rare genetic disorder
- chronic inflammation of the pancreas (chronic pancreatitis)
- had a part or the whole of their pancreas removed (partial or total pancreatectomy)
- cancer of the pancreas

Creon 20 000 can be used by children, adolescents and adults. The dosing in age groups is explained in section 3 of this leaflet, “How to take Creon”

Treatment with Creon improves the symptoms of pancreatic exocrine insufficiency including stool consistency (e.g. fatty stools), abdominal pain, flatulence and stool frequency (diarrhoea or constipation), independent of the underlying disease.

How Creon works

The enzymes in Creon work by digesting food as it passes through the gut. You should take Creon during or immediately after a meal or a snack. This will allow the enzymes to mix thoroughly with the food.

2. What you need to know before you take Creon

Do not take Creon

- if you are allergic to pancreas powder or to any of the other ingredients of Creon (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Creon.

Patients with cystic fibrosis

A rare bowel condition called “fibrosing colonopathy”, where your gut is narrowed, has been reported in patients with cystic fibrosis taking high dose pancreas powder 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**.

The dosing of lipase units is explained in section 3 of this leaflet, “How to take Creon”.

Severe allergic reaction

If an allergic reaction occurs, stop your treatment and talk to your doctor. An allergic reaction could include itching, hives or rash. Rarely, a more serious allergic reaction may include a feeling of warmth, dizziness and fainting, trouble breathing; these are symptoms of a severe, potentially life-threatening condition called ‘anaphylactic shock’. If this occurs, call for urgent medical attention straightaway.

Talk to your doctor if you are allergic to pig proteins before taking Creon.

Mouth irritation

Oral pain, irritation (stomatitis), bleeding, and ulcer formation in the mouth may occur in case the capsules are chewed and/or kept too long in the mouth. Rinsing the mouth and drinking of a glass of water may help if there are preliminary signs of mouth irritation.

Creon can only be sprinkled on certain food (see section 3 of this leaflet, “How to take Creon”).

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

Other medicines and Creon

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may become pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Your doctor will decide whether you can take Creon while being pregnant.

Creon can be used while breast-feeding.

Driving and using machines

Creon does not affect your ability to drive or operate tools or machines.

3. How to take Creon

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your dose is measured in 'lipase units'. Lipase is one of the enzymes in pancreas powder. 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:

- the severity of 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.

How much Creon to take

For patients with cystic fibrosis

Children:

This strength of the medicine may not be suitable for the initiation of therapy in children, depending on the child's age and weight.

The necessary dose for a child should be determined by the doctor with dosage forms containing less lipase units (e.g. 10,000 or 5,000 lipase units).

Once the dose per meal has been established, this strength of the medicine may be used in children.

- The usual starting dose for children under 4 years of age is 1000 lipase units per kilogram body weight per meal.
- The usual starting dose for children 4 years of age and over is 500 lipase units per kilogram body weight per meal.

Adolescents and adults:

Weight-based enzyme dosing should begin with 500 lipase units per kilogram bodyweight per meal in adolescents and adults.

For all age groups:

Your dose should not exceed 2,500 lipase units per kilogram bodyweight per meal or 10,000 lipase units per kilogram bodyweight per day or 4,000 lipase units per gram fat intake.

For patients with other problems of the pancreas

Adolescents and adults:

The usual dose for a meal is between 25,000 and 80,000 lipase units.

The usual dose for a snack is half the dose for a meal.

When to take Creon

Always take Creon during or immediately 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

- Creon should always be taken with a meal or snack.
- The capsules should be swallowed whole with a drink of water or juice.
- Do not crush or chew the capsules or its content as this can cause irritation inside your mouth or change the way Creon works in your body.
- If it is difficult to swallow the capsules, open them carefully and add the pellets to a small amount of soft acidic food or acidic liquids. Acidic soft foods could for example be yogurt or applesauce. Acidic liquids could be apple, orange or pineapple juice. Do not mix the pellets with water, milk including flavoured milk, breast milk and formula feeds or with hot food. Swallow the mixture immediately, without crushing or chewing and drink some water or juice.
- Mixing with non-acidic food or liquid, crushing or chewing of the pellets may cause irritation inside your mouth or change the way Creon works in your body.

- Do not hold Creon capsules or its content inside your mouth. Make sure the medicine and food mixture is swallowed completely and no pellets are left in your mouth.
- Do not store the mixture.

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 pancreas powder 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 take a double dose to make up for a forgotten dose.

If you stop taking Creon

Do not stop taking Creon without first talking to your doctor. Many patients will need to take Creon for the rest of their lives.

If you have any further questions on the use of this medicine, 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 may happen with this medicine.

The most important serious side effects seen with pancreatic enzyme replacement medicines are ‘anaphylactic shock’ and fibrosing colonopathy. These two side effects have occurred in a very small number of people, but their exact frequency is unknown.

Anaphylactic shock is a severe, potentially life-threatening allergic reaction that can develop rapidly.

If you notice any of the following seek urgent medical attention straightaway:

- itching, hives or rash
- swollen face, eyes, lips, hands or feet
- feeling lightheaded or faint
- trouble breathing or swallowing
- palpitations
- dizziness, collapse or unconsciousness

Repeated high doses of pancreatic enzyme replacement medicines can also cause scarring or thickening of the bowel wall that can lead to blockage of the intestines, a condition called fibrosing colonopathy. If you have severe stomach pain, trouble passing stools (constipation), nausea or vomiting, tell your doctor straightaway.

Very common side effects (may affect more than 1 in 10 people)

- pain in your stomach (abdomen).

Common side effects (may affect up to 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.

Uncommon side effects (may affect up to 1 in 100 people)

- rash.

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 HPRAs Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Creon

Keep this medicine out of sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the pack. The expiry date refers to the last day of that month.

Do not store above 25°C.

After opening do not store above 25 °C and use within 6 months. Keep the container tightly closed to protect from moisture.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. 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 pancreas powder.

- Each Creon 20 000 capsule contains 300 mg pancreas powder corresponding to (Ph.Eur. units):
 - Lipase 20,000
 - Amylase 16,000
 - Protease 1,200

- The other ingredients are:

Capsule content:

- Hypromellose phthalate
- Macrogol 4000
- Triethyl citrate
- Dimethicone 1000
- Cetyl alcohol

Capsule shell:

- Gelatin
- Iron oxides red, yellow and black (E 172)
- Sodium laurylsulphate
- Titanium dioxide (E 171)

What Creon looks like and contents of the pack

Creon 20 000 capsules are size 0 elongated. They are brown and transparent. They contain brownish gastro-resistant pellets (minimicrospheres).

Creon 20 000 is available in HDPE bottles with PP twist-off closure with 50 capsules, 60 capsules, 100 capsules, 120 capsules, 200 capsules, 250 capsules.

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Viatrix Healthcare Limited,
Damastown Industrial Park,
Mulhuddart Dublin 15,
DUBLIN Ireland

Manufacturer:
 Abbott Laboratories GmbH
 Justus-von-Liebig-Str. 33
 31535 Neustadt
 Germany

Mylan Germany GmbH
 Lütticher Straße 5
 53842 Troisdorf
 Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

| Member State | Product (invented) name |
|----------------|---|
| Austria | KREON 20.000 Einheiten - Kapseln |
| Belgium | Creon 20.000, 300 mg, maagsapresistente capsules, hard |
| Bulgaria | Креон 20 000 стомашно-устойчиви капсули, твърди |
| Croatia | KREON® 20 000 želučanootporne kapsule, tvrde |
| Cyprus | Creon 20.000 |
| Czech Republic | Kreon 20 000 enterosolventní tvrdé tobolky |
| Denmark | Creon 20.000 |
| Estonia | Kreon 20 000 U |
| Finland | Creon 20 000 enterokapseli, kova |
| France | CREON 20 000 U, gélule gastro-résistante |
| Germany | Kreon 20 000 Ph. Eur. Lipase Einheiten, magensaftresistente Hartkapseln |
| Greece | Creon-P 20.000 gastro-resistant capsule, hard |
| Hungary | Kreon 20 000 egység gyomornedv-ellenálló kemény kapszula |
| Iceland | Creon 20.000 sýrupolin hylki, hörð |
| Ireland | Creon 20000 gastro-resistant capsules, hard |
| Italy | CREONIPÉ 20000 U.Ph.Eur. capsule rigide gastroresistenti |
| Latvia | Kreon 20 000 V zarnās šķīstošās cietās kapsulas |
| Lithuania | Kreon 20 000 V skrandyje neirios kietosios kapsulės |
| Luxembourg | Creon 20000, 300 mg, gélules gastro-résistantes |
| Malta | Creon® 20000 Capsules |
| Netherlands | Creon 20.000, harde maagsapresistente capsules 20.000 eenheden |
| Norway | Creon 20 000 harde enterokapsler |
| Poland | Kreon Travix Max |
| Portugal | KREON 20000, Cápsula gastro-resistente |
| Romania | KREON 20000 capsule gastrorezistente |
| Slovakia | Kreon 20 000, tvrdé gastrorezistentné kapsuly |
| Slovenia | Kreon EPI 20 000 Ph.Eur.e. trde gastrorezistentne kapsule |
| Spain | Kreon 20.000 U cápsulas duras gastrorresistentes |
| Sweden | Creon 20000 enterokapslar, hårda |
| United Kingdom | Creon® 20000 Capsules |

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