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   Abdominal symptoms (such as abdominal pain).
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   How and where to keep your capsules.

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   When you should take Creon 10000.
   How to store Creon 10000.
   The ingredients in Creon 10000.
   More information about cystic fibrosis and pancreatitis.

4. Possible side effects

5. How to take Creon 10000
   Do not take Creon 10000 if:
   You are allergic to pork, any pig product, or to any of the other ingredients.
   If the above applies to you take Creon 10000.
   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 yogurt).
   If you have cystic fibrosis and take in excess of 10,000 fucose units per kilogram per day and have unusual abdominal symptoms or changes in abdominal symptoms tell your doctor.
   Talk to your doctor if:
   • you are pregnant or trying to get pregnant (Creon 10000 can be used while breast-feeding)
   • you have cystic fibrosis
   • you are allergic to pork
   • you are allergic to any pig product
   • you are allergic to any of the other ingredients

6. Further information

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.

About Creon 10000

Creon 10000 is a 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 10000 capsules contain a mixture of the natural enzymes which are used to digest food.
The enzymes are taken from pig pancreas glands.

How does Creon 10000 work?
The enzymes in Creon 10000 work by digesting food as it passes through the gut. So, you must take Creon 10000 at the same time as eating a meal or a snack. This will allow the enzymes to mix thoroughly with the food.

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If you drive or use machines
It is unlikely that Creon 10000 will affect your ability
to drive or operate tools or machines.

When to take Creon 10000
Always take Creon 10000 during or immediately after eating a meal or a snack and drink plenty of
water (see section 4).

How to take Creon 10000
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 yogurt).
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.
How long to take Creon 10000 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 10000
If you take too much Creon 10000 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 10000 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 10000 – contact your doctor.

Very common side effects (affect more than 1 in 10 patients):
- stomach pains
- diarrhoea
- constipation

Common side effects (affect 1–10 patients out of 100):
- feeling or being sick
- bloating

Uncommon side effects (affect 1–10 patients out of 100):
- 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.

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 the national reporting system listed below.

In the UK:
The Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

In Malta:
ADR Reporting
The Medicines Authority
Post-Licensing Directorate
203 Level 3, Rue D’Argens
GZR-1368 Gżira

Website: www.medicinesauthority.gov.mt
e-mail: postlicensing.medicinesauthority@gov.mt
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Creon 10000

How and where to keep your capsules
Keep this medicine out of the sight and reach of children.

Do not store above 25ºC 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 on the bottle. Once opened, use within 3 months.

Return all unused medicine to your pharmacist.

6. Further information

The ingredients in Creon 10000

The active ingredient in Creon 10000 is pancreatic. Each capsule contains enteric coated brownish-coloured granules (micromicrospheres) containing pancreatin 150 mg, equivalent to:

List of Enzymes: (Ph Eur units per capsule)
Lipase 10,000
Amylase 8,000
Protease 600

The granules are coated with a mixture of the following ingredients: macrogol 4000, hypromellose phthalate, dimethicone, triethyl citrate and cetyl alcohol.
The capsules contain: gelatin, iron oxides (E172), titanium dioxide (E171) and sodium lauryl sulfate.
Creon 10000 is available in 100, 250 or 300 capsule packs. Not all pack sizes may be marketed.
The Marketing Authorisation Holder is:
Mylan Products Ltd.
20 Station Close, Potters Bar,
Herts, EN6 1TL, UK
The Manufacturer is:
Abbott Laboratories GmbH
31535 Neustadt a. Rhde, 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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If you wish to receive this PL in Braille, large font or audio format please contact 023 8046 7000.
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Mylan
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