

**IMPORTANT THINGS YOU SHOULD KNOW ABOUT
CREON 10000 GASTRO-RESISTANT CAPSULES**

- Creon 10000 is a pancreatic enzyme supplement for people whose bodies do not make enough enzymes to digest their food.
- Take the amount of capsules as prescribed by your doctor or dietician.
- Take Creon 10000 with a meal or a snack and drink plenty of water.
- Do not take Creon 10000 if you are allergic to pork or any pig product.
- If you experience severe abdominal pain while taking Creon 10000, contact your doctor immediately.
- Most people do not have problems taking Creon 10000 but side effects can occur. (see section 4)

Please read the rest of this leaflet carefully before you start taking these tablets. It includes other important information on the safe and effective use of this medicine that might be especially important for you.

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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.

1. About Creon 10000

What is Creon 10000

Creon 10000 is a high strength 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 granules contain a mixture of the natural enzymes which are used to digest food. The enzymes are extracted from pig pancreas glands.

How does Creon 10000 work?

The enzymes in Creon 10000 work by digesting food as it passes through the gut. It is therefore essential that Creon 10000 is taken at the same time as eating a meal or a snack. This will allow the enzymes to mix thoroughly with the food.

2. Before you take Creon 10000

Do not take Creon 10000 if any of the following apply to you:

- Have you been told by your doctor that you are in the early stages of inflammation of the pancreas (acute pancreatitis)?
- Are you allergic to pork or any pig product?

If you have answered **Yes** to any of these questions: **Do not** take Creon 10000. Talk to your doctor or dietician again.

Talk to your doctor:

- If you are pregnant
- If you are trying to get pregnant
- If you are breast feeding

Please tell your doctor, dietician, or pharmacist if you think that you should not take Creon 10000 for any other reason.

3. How to take Creon 10000

How much Creon 10000 to take

- **Always follow your doctor or dietician's advice on how many capsules to take.**
- If your doctor advises you to increase the number of capsules you take, you should do so slowly. If you still have fatty stools or abdominal pain, talk to your doctor or dietician.

When to take Creon 10000

- Always take Creon 10000 at the same time as eating a meal or a snack and drink plenty of water (see section 1).

How to take Creon 10000

- Swallow the capsules whole or
- Open the capsules and mix the granules with soft food. Swallow the mixture straight away, without chewing.
- Drink plenty of liquid every day.

You should keep taking your medicine for as long as your doctor advises.

If anyone takes too much Creon 10000

If anybody takes too much Creon 10000 they should drink plenty of water and see their 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 prolonged abdominal pain, contact your doctor immediately.

Fibrosing colonopathy

A rare bowel disorder called fibrosing colonopathy was reported in a small number of children, with cystic fibrosis, taking large doses of both high and low-strength enzymes.

This is **not** known to happen to children taking Creon 10000.

But if you notice any **unusual abdominal symptoms** while taking Creon 10000 – contact your doctor.

Uncommon side effects (1 in 500 patients):

Inform your doctor

These side effects may affect about one in 500 people taking Creon 10000:

- diarrhoea
- constipation
- stomach pains
- feeling sick
- skin reactions, such as a rash or itching.

Rare side effects (less than 1 in 1000 patients):

These may affect less than one in a thousand people taking Creon 10000:

- developing high levels of uric acid in their blood and urine

If you notice any unwanted effect (even one not mentioned in this leaflet), or if you feel unwell while taking Creon 10000: **Tell your doctor.**

If you drive or operate machinery

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

5. More information about Creon 10000

How and where to keep your capsules

Keep all medicines where children cannot reach or see them – preferably locked in a cupboard or medicine cabinet.

Do not store above 30°C and keep in the original container. Keep 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 over labelled container and bottle located after Exp. date.

Return all unused medicine to your pharmacist. 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 protect the environment.

The ingredients in Creon 10000

The active ingredient in Creon 10000 is pancreatin. Each capsule contains gastro-resistant brownish-coloured granules (minimicrospheres) containing pancreatin 150mg, equivalent to:

List of Enzymes: (PhEur Units per Capsule)

Lipase 10,000

Amylase 8,000

Protease 600

The granules are coated with a mixture of the following ingredients: macrogol 4000, triethy citrate, hypromellose phthalate, cetyl alcohol and dimeticone.

The capsules contain: gelatin, iron oxides (E172), titanium dioxide (E171) and sodium lauril sulfate.

Creon 10000 is available in 100 capsule packs.

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

WHO HAS MADE YOUR MEDICINE?

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

Procured from within the EU by the parallel product authorisation holder: McDowell Pharmaceuticals, 4 Altona Road, Lisburn, N. Ireland BT27 5QB, and repackaged by: NG Limited, Units 8-12, Cornwall Road Industrial Estate, Smetwick, West Midlands B66 2JT, United Kingdom.

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