

Patient Information Leaflet
Creon[®] Micro granules
(pancreatin)

The name of your medicine is Creon Micro granules but will be referred to as Creon Micro throughout this leaflet.

Important things you SHOULD know about Creon Micro

- Creon Micro is a pancreatic enzyme supplement for people whose bodies do not make enough enzymes to digest their food.
- **Give** the amount of granules prescribed by your doctor.
- **Give** Creon Micro during or immediately after a meal or a snack and provide plenty of water.
- **Do not give** Creon Micro if the patient is allergic to pork, any pig product or any of the ingredients of Creon Micro (listed in section 6).
- If the patient experiences **severe abdominal pain** while taking Creon Micro, contact a doctor immediately.
- Most people do not have problems taking Creon Micro but side effects can occur (see section 4).

Please read the rest of this leaflet carefully before you start giving these granules.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask a doctor or pharmacist.
- Do not pass it on to others. It may harm them, even if their symptoms are the same.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell a doctor or pharmacist.

How to find the information you need

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How you should give Creon Micro.
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The ingredients in Creon Micro.
More information about cystic fibrosis and pancreatitis.

1. About Creon Micro

What is Creon Micro

- Creon Micro 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 Micro contains a mixture of the natural enzymes which are used to digest food.
- The enzymes are taken from pig pancreas glands.

How does Creon Micro work?

The enzymes in Creon Micro work by digesting food as it passes through the gut. So you must give Creon Micro with a meal or a snack. This will allow the enzymes to mix thoroughly with the food.

2. Before you give Creon Micro

Do not give Creon Micro if:

- The patient is allergic (or hypersensitive) to pork, any pig product or any of the ingredients of Creon Micro (listed in section 6).

If the above applies to the patient, do not give Creon Micro. Talk to the doctor or dietician again.

When you need to take special care with Creon Micro

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

Talk to the doctor, if:

- you are pregnant or trying to get pregnant (Creon Micro can be used while breast-feeding)

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

If the patient drives or uses machinery

It is unlikely that Creon Micro will affect the patient's ability to drive or operate tools or machines.

Sodium content

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

3. How to give Creon Micro

How much Creon Micro to give

- **Always follow the doctor or dietician's advice on how many granules to give.**
- The usual starting dose is 100mg (one measure). The maximum amount you may give should not be greater than 10,000 units lipase/kg/day.
- If the doctor advises you to increase the dose you give, you should do so slowly.

If the patient still has fatty stools or abdominal pain, talk to the doctor or dietician.

When to give Creon Micro

- Always give Creon Micro during or immediately after a meal or a snack and provide plenty of water (see section 1).

How to take Creon Micro

- Mix the granules (without crushing) with acidic liquid (e.g. apple, orange or pineapple juice) or soft food (e.g. apple sauce or yoghurt).
- 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 Micro works in your body.
- Do not hold Creon Micro in your mouth.
- Do not store the mixture.

How to give Creon Micro to babies and infants

- Mix the granules (without crushing) with a small amount of apple juice and give from a spoon directly before the feed.
- Alternatively mix the granules on a spoon (without crushing) with a small amount of baby's usual milk and give to the infant immediately. Do not add the granules to the baby's bottle.
- Make sure the infant swallows all the granules immediately and none are left in the mouth.
- Provide plenty of liquid every day.
- Mixing with non-acidic food or liquid, crushing or chewing of the pellets may cause mouth irritation or change the way Creon Micro works in the body.
- Do not store the mixture.

Weaned infants

- Mix the granules (without crushing) with acidic liquid (e.g. apple, orange or pineapple juice) or soft food (e.g. apple sauce or yoghurt).

- Alternatively mix the granules on a spoon (without crushing) with a small amount of baby's usual milk and give to the infant immediately. Do not add the granules to the baby's bottle.
- Make sure the infant swallows all the granules immediately, without chewing and none are left in the mouth.
- Provide plenty of liquid every day.
- Mixing with non-acidic food or liquid, crushing or chewing of the pellets may cause mouth irritation or change the way Creon Micro works in the body.
- Do not store the mixture.

How long to give Creon Micro

You should keep giving the medicine until the doctor tells you to stop. Many patients will need to take pancreatic enzyme supplements for the rest of their lives.

If you give the patient too much Creon Micro

If you give the patient too much Creon Micro, he/she should drink plenty of water and see the doctor immediately.

If you forget a dose

If you forget to give the medicine, wait until the next meal and give the usual dose. Do not try to make up for the dose that you have missed. **Just give the next dose at the usual time.**

4. Possible side effects

Like all medicines, Creon Micro can cause side effects (unwanted effects or reactions), but not everyone gets them.

If the patient has severe or long-lasting abdominal pain, contact the doctor immediately.

If you notice **any unusual abdominal symptoms** while taking Creon Micro-contact the doctor.

Very common side effects (more than 1 in 10 patients):

- Stomach pains

Common side effects (affect 1–10 patients out of 100):

- Diarrhoea
- Constipation
- Feeling or being sick

- Bloating

Uncommon side effects (affect 1–10 patients out of 1000):

- 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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Creon Micro

Keep out of the sight and reach of children
Do not store above 25°C.

Keep the container tightly closed in order to protect from moisture.

Store in the original container.

The enzymes in Creon Micro 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.

Take Creon Micro within 12 weeks of opening the container.

Do not take the granules after the expiry date which is stated on the carton and bottle labels after 'Exp'. The expiry date refers to the last day of that month.

If the granules become discoloured or shows any signs of deterioration, seek the advice of your pharmacist.

Remember if your doctor tells you to stop taking this medicine, return any unused granules to your pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.

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. Further information

What Creon Micro contains

The active ingredient in the Creon Micro is pancreatin.

One measure of granules contains 60.12mg of pancreatin, equivalent to the following list of enzymes:

(Ph.Eur. Units per measure (100mg))

Lipase	5,000
Amylase	3,600
Protease	200

The other ingredients are macrogol 4000, hypromellose phthalate, cetyl alcohol, triethyl citrate and dimeticone 1000.

What Creon Micro looks like and the contents of the pack

Creon Micro are round, light-brown gastro-resistant granules in a glass bottle with a scoop measure (100mg) and are available as bottles of 20g (containing about 200 measures).

Manufactured by: Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover, Germany.

Procured from within the EU and repackaged by the Product Licence holder:

B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Creon® Micro granules; PL 18799/2788

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