

PACKAGE LEAFLET: INFORMATION FOR THE USER
Creon for Children 5000 Gastro-resistant Granules
Pancreatin

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.

In this leaflet:

1. What Creon for Children is and what it is used for
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1. WHAT CREON FOR CHILDREN IS AND WHAT IT IS USED FOR

What Creon for Children is

- Creon for Children contains an enzyme mixture called “pancreatin”.
- Pancreatin helps you digest food. The enzymes are taken from pig pancreas glands.
- The small pellets of Creon for Children slowly release the pancreatin in your gut (gastro-resistant pellets, called Minimicrospheres™).
- Creon for Children is for children and infants who cannot swallow capsules. It is used when low doses of pancreatin are needed.

What Creon for Children is used for

- Creon for Children is intended for use in children and infants with “pancreatic exocrine insufficiency”. This is when their pancreas gland does not make enough enzymes to digest food.

How Creon for Children works

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

2. BEFORE YOU TAKE CREON FOR CHILDREN

Do not take Creon for Children if:

- you are allergic (hypersensitive) to pig pancreatin or to any of the other ingredients of Creon for Children (listed in section 6).

If you are not sure, talk to your doctor or pharmacist before taking Creon for Children.

When you need to take special care with Creon for Children

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 for Children.

However, if you have cystic fibrosis and take in excess of 10000 lipase units per kilogram per day and have unusual abdominal symptoms or changes in abdominal symptoms **tell your doctor.**

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

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Fertility, pregnancy and breast-feeding

- Talk to your doctor before taking this medicine if you are pregnant or might become pregnant. Your doctor will decide if you should take Creon for Children and at which dose. Creon for Children can be used while breast-feeding.

Driving and using machines

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

3. HOW TO TAKE CREON FOR CHILDREN

Always take Creon for Children exactly as your doctor has told you. You should check with your doctor if you are not sure.

How much Creon for Children to take

- Your dose is measured in ‘lipase units’. Lipase is one of the enzymes in pancreatin.
- Always follow your doctor’s advice on how much Creon for Children to take.
- Always use the scoop that comes with the bottle of Creon for Children. One scoop contains 5000 lipase units.
- The usual starting dose is one scoop with each meal.
- 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.

When to take Creon for Children

Always take Creon for Children 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 for Children

- 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.
- Alternatively mix the granules (without crushing) with a small amount of baby's usual milk on a weaning spoon and give to the infant immediately. Do not add the granules to the baby's bottle.
- Care should be taken that no product is retained in the mouth.
- Make sure all of the pellets are swallowed and none are left in the mouth.
- As a general rule, drink plenty of liquid every day.

How long to take Creon for Children for

Take Creon for Children until your doctor tells you to stop. Many patients will need to take Creon for Children for the rest of their lives.

If you take more Creon for Children than you should

If you take more Creon for Children 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 for Children

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 for Children

Do not stop taking Creon for Children 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 for Children can cause side effects, although not everybody gets them.

If you experience any of the following serious side effects, stop taking this medication and seek urgent medical attention immediately:

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.

Other possible side effects include:

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. During studies, the number of patients taking Creon for Children who had pain in their stomach or diarrhoea was similar or lower than in patients not taking Creon for Children.

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

- rash.

Not known (frequency cannot be estimated from the available data)

- severe itching (pruritus)
- hives (urticaria).

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 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 FOR CHILDREN

- Keep out of the sight and reach of children.
- Do not store above 25°C. After opening use within 12 weeks.
- Keep the container tightly closed to protect from moisture.
- Do not take Creon for Children after the expiry date, which is stated on the container. The expiry date refers to the last day of that month.
- 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 for Children contains

- The active ingredient in Creon for Children is pancreatin.
- Each scoop contains 100 mg of minimicrospheres. This contains 60.12 mg pancreatin corresponding to (Ph.Eur. units):
 - Lipase 5000
 - Amylase 3600
 - Protease 200
- The other ingredients are:
 - macrogol 4000, hypromellose phthalate, dimethicone, triethyl citrate, cetyl alcohol

What Creon for Children looks like and the contents of the pack

- The Creon for Children gastro-resistant pellets (Minimicrospheres™) are round and light brown.

- Creon for Children is available in glass bottles of 20 g. The bottle comes in a carton box with a scoop.

Marketing Authorisation Holder

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

Manufacturer

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

This leaflet was last approved in June 2023.

More information about cystic fibrosis

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.