

NEW ZEALAND CONSUMER MEDICINE INFORMATION

CREON[®] MICRO

Pancreatin modified release granules



What is in this leaflet

Please read this leaflet carefully before you start taking Creon Micro.

This leaflet answers some common questions about Creon Micro.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you taking Creon Micro against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Creon Micro is used for

Creon Micro is a pancreatic enzyme used to treat conditions associated with pancreatic exocrine insufficiency, such as:

- Cystic fibrosis
- Chronic pancreatitis
- Various upper gastrointestinal surgery

People with pancreatic exocrine insufficiency often suffer with symptoms of:

- abdominal pain
- diarrhoea
- steatorrhoea (foul fatty stools which float in the toilet)
- bloating
- weight loss

These symptoms appear because the body is unable to digest food normally. When this happens, your body's ability to absorb important nutrients from food is impaired and leads to malnutrition. If left untreated these symptoms can affect your quality of life and a poor nutritional status could have long term health implications.

Creon Micro contains digestive enzymes (amylase, lipase and protease) extracted from pancreas of pigs.

It works by restoring normal digestive action in your body to relieve abdominal symptoms and improve nutritional status.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor or pharmacist if you have any questions about why this medicine has been advised for you.

There is no evidence that Creon Micro granules are addictive.

This medicine is not expected to affect your ability to drive a car or operate machinery.

Before you take Creon Micro

When you must not take it

Do not take Creon Micro if you have an allergy to:

- any medicine containing pancreatic enzymes
- pork or other pig products
- any of the ingredients listed at the end of this leaflet.

Some symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty

breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Creon Micro.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are taking Creon Micro.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Creon Micro

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much Creon Micro to take or give to your child. Do not increase the number of doses yourself without informing your doctor.

Your doctor has prescribed a dose of Creon Micro for you or your child which is specifically tailored to the severity of the condition.

For patients with cystic fibrosis, your doctor will have determined a dose specific to your body weight and condition.

The starting dose for infants with cystic fibrosis should start at a dose of 2000 to 5000 lipase units for each feeding (usually 120 mL) and adjusted to a dose no greater than 2500 lipase units per kilogram per feeding.

For children less than 4 years old, dosing should begin with 1000 lipase units per kilogram per meal, and 500 lipase units per kilogram per meal for children over the age of 4.

The maximum recommended dose of lipase in infants and children with cystic fibrosis is 10,000 lipase units per kilogram body weight per day.

Dosing in other conditions associated with exocrine pancreatic insufficiency ranges from about 25,000 to 80,000 lipase units per meal and half of the dose for snacks.

Patients who use more than 10,000 units of lipase per kilogram per day, will probably be monitored closely by their doctor.

Your doctor may need to make a number of adjustments before determining the right dose which suits you best.

It is normally not necessary to restrict your diet of fat while you are taking Creon Micro as your symptoms will usually be under control. In people with malnutrition, getting enough fat in the diet will help improve nutrition. If unsure, you should consult your doctor or dietitian regarding your diet whilst on Creon Micro.

If the doctor advises you to increase the dosage, you should increase it slowly. A very rapid increase in dosage may lead to constipation. If you are unsure how to increase the dose, ask your doctor or pharmacist to explain it to you.

How to take it

The small measuring scoop that is provided with the bottle is designed to contain dose of 100 mg of granules, equivalent to 5000 units of lipase.

Creon Micro can be added to small amounts of acidic soft food that do not require chewing, such as apple sauce, yogurt or fruit juice.

For infants, Creon Micro can be mixed with a small amount of milk on a weaning spoon immediately before the feed. Do not add to baby's bottle.

Any mixture of Creon Micro with soft food or fluid should be swallowed immediately and not stored.

Do not crush or chew the granules, swallow the granules whole followed by juice or water, to ensure complete ingestion. The granules have a special coating to stop them dissolving until they have gone through the stomach and into the intestines where they work.

Make sure to drink plenty of liquid every day while taking Creon Micro.

When to take it

Take Creon Micro with every meal and snack.

How long to take it?

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

Wait until your next meal or snack and take your usual number of doses.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking Creon Micro

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Creon Micro.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

Make sure you tell your doctor if you are still having problems with fatty stools or abdominal pain while you are taking Creon Micro.

Drink plenty of water every day when you are taking Creon Micro.

Follow your doctor's instructions carefully and do not stop taking Creon Micro unless told to do so by a doctor.

Things you must not do

Do not take Creon Micro to treat any other complaints unless your doctor tells you to.

Do not give Creon Micro to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things that would be helpful for your condition

Diet should be considered as part of your overall management plan. Talk to your doctor or dietician for more information and advice.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Creon Micro. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Extremely high doses of pancreatin have been associated with excessive amounts of uric acid in the urine and the blood.

If you take too much Creon Micro you may get irritation or inflammation in the anal region.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Creon Micro.

This medicine helps most people with insufficient enzymes to digest their food, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are

serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- stomach or bowel problems, including:
 - diarrhoea
 - constipation
 - abnormal stools
 - abdominal discomfort
 - nausea
 - vomiting
- skin reactions

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

An allergic reaction, symptoms include:

- wheezing
- difficulty breathing
- swelling of face, lips, tongues or other part of the body
- shortness of breath

Tell your doctor immediately if you have severe or prolonged abdominal pain.

Patients with cystic fibrosis taking high doses of pancreatic enzyme supplements have suffered from narrowing of the bowel and required an operation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

In rare cases, people taking very high doses may develop high levels of uric acid in their blood and urine.

Other side effects not listed above may also occur in some people. Tell your doctor or pharmacist if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking Creon Micro

Storage

Keep your granules in the bottle until it is time to take them.

If you take the granules out of the bottle they may not keep well.

Keep your granules in a cool dry place where the temperature stays below 25°C. Protect from moisture.

Once open, use within 3 months.

Do not store Creon Micro or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Creon Micro is a round light brown minimicrosphere. Available in bottles of 200 scoop measures, with dosing scoop.

Ingredients

Active ingredient(s):

Each 100 mg (equivalent to one measuring dosing spoon) of Creon Micro contains 60.12 mg of pancreatin as the active ingredient, equivalent to Lipase 5000 Ph. Eur. units, Amylase 3600 Ph. Eur. units and Protease 200 Ph. Eur. units.

Inactive ingredient(s):

Creon Micro also contains:

- Cetyl alcohol
- Dimeticone

- Hypromellose phthalate
- Macrogol 4000
- Triethyl citrate

This medicine does not contain lactose or gluten.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Creon Micro is supplied in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland
NEW ZEALAND

Telephone: (09) 579 2792

Date of Preparation

8 January 2020
(Based on datasheet dated 27
December 2019)