

CREON[®] MICRO

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using CREON MICRO?

CREON MICRO contains the active ingredient Pancreatic Extract. CREON MICRO is used in a condition called pancreatic exocrine insufficiency where the body does not make enough enzymes to digest food.

For more information, see Section [1. Why am I using CREON MICRO?](#) in the full CMI.

2. What should I know before I use CREON MICRO?

Do not use if you have ever had an allergic reaction to CREON MICRO or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use CREON MICRO?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CREON MICRO and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use CREON MICRO?

- Your doctor has prescribed a dose of CREON MICRO for you or your child which is specifically tailored to the severity of the condition. 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.
- The small measuring scoop that is provided with the bottle is designed to contain a dose of 100 mg of granules. This amount provides 5,000 units of lipase.

More instructions can be found in Section [4. How do I use CREON MICRO?](#) in the full CMI.

5. What should I know while using CREON MICRO?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using CREON MICRO.• Drink plenty of water every day when you are taking CREON MICRO.• Call your doctor straight away if you are still having problems with fatty stools or abdominal pain while you are taking CREON MICRO.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking CREON MICRO unless told to do so by your doctor.• Do not use this medicine for any purpose other than for the purpose it has been recommended for you.
Driving or using machines	<ul style="list-style-type: none">• CREON MICRO has no influence on the ability to drive and use machinery.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Keep your CREON MICRO in a cool dry place where the temperature stays below 25°C. Please note that in warmer climates it may be necessary to store CREON MICRO in the refrigerator.• After opening use within 3 months.

For more information, see Section [5. What should I know while using CREON MICRO?](#) in the full CMI.

6. Are there any side effects?

Speak to your doctor if you experience stomach or bowel problems, including diarrhoea, constipation, abnormal stools, abdominal discomfort, nausea and skin reactions. Seek immediate medical attention if you experience severe or prolonged abdominal pain.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

CREON[®] MICRO

Active ingredient(s): *Pancreatic Extract*

Consumer Medicine Information (CMI)

This leaflet provides important information about using CREON MICRO. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using CREON MICRO. Please read this leaflet before you start taking CREON MICRO.** If you are helping someone else to take CREON MICRO, please read this leaflet before you give the first dose.

Where to find information in this leaflet:

- [1. Why am I using CREON MICRO?](#)
- [2. What should I know before I use CREON MICRO?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use CREON MICRO?](#)
- [5. What should I know while using CREON MICRO?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using CREON MICRO?

CREON MICRO contains the active ingredient **Pancreatic Extract**. CREON MICRO is a pancreatic enzyme supplement.

CREON MICRO is used in a condition called **pancreatic exocrine insufficiency** where the body does not make enough enzymes to digest food. This condition appears in a number of different patients including those with cystic fibrosis, chronic pancreatitis, or patients who have had upper gastrointestinal surgery. People with a deficiency of pancreatic enzymes often suffer with symptoms of diarrhoea, steatorrhoea (foul fatty stools which float in the toilet), bloating and 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. The supplementation of pancreatic enzymes using CREON helps restore the normal digestive action in your body to relieve abdominal symptoms and improve nutritional status.

The enzymes are extracted from pancreas of pigs.

CREON MICRO is approved for the uses listed above. However, your doctor may prescribe this medicine for another use. If you would like more information, ask your doctor.

There is no evidence that CREON MICRO is addictive.

2. What should I know before I use CREON MICRO?

Warnings

Do not use CREON MICRO if:

- you are allergic to pork, other pig products, or any of the ingredients listed at the end of this leaflet.
- always check the ingredients to make sure you can use this medicine.
- the packaging is torn or shows signs of tampering.
- the expiry date has passed, it may not work as well.

Check with your doctor if you:

- are allergic to any other medicines or any foods, dyes or preservatives.
- take any medicines for any other condition
- are pregnant, planning to become pregnant, are breast feeding or intend to breast feed.

Your doctor will discuss whether you should take this product.

If you have not told your doctor about any of the above, tell them before you take CREON MICRO.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

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

Some medicines may interfere with CREON MICRO and affect how it works.

You should avoid taking antacids, which are medicines that are used to treat heartburn and indigestion, at the same time as when taking CREON MICRO. Antacids may affect how well CREON MICRO work by breaking down the special coating used to protect the pancreatic enzymes. If it is necessary to take an antacid, then it should be taken at least one hour before you take your CREON MICRO.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CREON MICRO.

4. How do I use CREON MICRO?

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.
- 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.
- The maximum recommended dose of lipase in infants and children with cystic fibrosis is 10,000 units per kilogram body weight in 24 hours.
- Patients who use more than 10,000 units per kilogram per day, will probably be monitored closely by their doctor.
- Follow the instructions provided by your doctor and use CREON MICRO until your doctor tells you to stop. These directions may differ from the information in this leaflet.

When to take CREON MICRO

- CREON MICRO should be taken with every meal and snack.

How to take CREON MICRO

- The small measuring scoop that is provided with the bottle is designed to contain a dose of 100 mg of granules. This amount provides 5,000 units of lipase.
- CREON MICRO can be added to small amounts of acidic soft food that do not require chewing such as apple juice or mashed bananas. The mixture of CREON MICRO and soft food should be swallowed immediately without crushing or chewing and followed with water or juice to ensure complete ingestion. Care should be taken to ensure that no drug is retained in the mouth.
- In young infants, CREON MICRO should be mixed with a small amount of apple juice and given from a spoon directly before the feed. In young infants, granules should be taken with acidic liquids or soft foods (e.g. mixed with apple juice or apple puree), but without chewing, directly before the meal. When giving CREON MICRO to young infants the apple juice should not be diluted.
- When you are taking CREON MICRO, it is important to make sure that you drink plenty of liquid every day.

If you forget to use CREON MICRO

CREON MICRO should be used regularly at the same time each day. If you miss your dose at the usual time, wait until your next meal or snack and take your usual number of doses.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

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

If you use too much CREON MICRO

If you think that you have used too much CREON MICRO, you may need urgent medical attention.

You should immediately:

- Drink plenty of water and
- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using CREON MICRO?

Things you should do

Follow your doctor's instructions carefully and do not stop taking CREON MICRO unless told to do so by your doctor.

Drink plenty of water every day when you are taking CREON MICRO.

Call your doctor straight away if you:

- are still having problems with fatty stools or abdominal pain while you are taking CREON MICRO.
- are about to start taking any new medicines, tell your doctor and pharmacist that you are taking CREON MICRO.

Remind any doctor, dentist or pharmacist you visit that you are using CREON MICRO.

Things you should not do

- Do not give CREON MICRO to anyone else, even if they have the same condition as you.
- Do not use this medicine for any purpose other than for the purpose it has been recommended for you.
- Do not use more than the recommended amount.
- Do not stop taking your medicine until your doctor tells you to do so.
- Do not let yourself run out of medicine unless told to do so by your doctor.

Things that may help your condition

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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how CREON MICRO affects you.

CREON MICRO has no influence on the ability to drive and use machinery.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep the container tightly closed in order to protect from moisture.
- Keep your CREON MICRO in a cool dry place where the temperature stays below 25°C. Please note that in warmer climates it may be necessary to store CREON MICRO in the refrigerator.
- After opening use within 3 months.
- A locked cupboard at least one-and half metres above the ground is a good place to store medicines.

Follow the instructions in the carton on how to take care of your medicine properly.

Heat and dampness can destroy some medicines.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

After opening use within 3 months.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Stomach or bowel problems, including: <ul style="list-style-type: none">• diarrhoea• constipation• abnormal stools• abdominal discomfort• nausea	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
Skin reactions	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Severe or prolonged abdominal pain Irritation or inflammation in the anal region <ul style="list-style-type: none">• If you take too much CREON MICRO you may get irritation or inflammation in the anal region.	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

The active ingredient in CREON MICRO is an extract of pancreatic powder of porcine origin (pigs), therefore the presence of porcine parvovirus or other porcine viruses cannot be totally excluded. However, there is no evidence of transmission of these viruses to humans or of porcine pancreatic powder extracts causing illness in humans.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What CREON MICRO contains

Active ingredient (main ingredient)	Each dosing unit of 100 mg of CREON MICRO contains
	Pancreatic Extract 60.12 mg equivalent to not less than 5,000 Ph.Eur. units lipase, 3,600 Ph.Eur. units amylase and 200 Ph. Eur. units protease.

Other ingredients (inactive ingredients)	macrogol 4000 hypromellose phthalate cetyl alcohol triethyl citrate dimeticone 1000
Potential allergens	Contains phenylalanine.

One dosage unit is measured with a measuring scoop as dosing device.

Do not take this medicine if you are allergic to any of these ingredients.

What CREON MICRO looks like

CREON MICRO is a round, light brown enteric-coated granules in glass bottles. Each glass bottle contains 20g of enteric-coated granules. Measuring scoop supplied (AUST R 166118).

Who distributes CREON MICRO

Viatrix Pty Ltd
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30-34 Hickson Road
Millers Point NSW 2000
www.viatrix.com.au

Phone: 1800 274 276

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