

# CREON<sup>®</sup> 10,000, CREON<sup>®</sup> 25,000, CREON<sup>®</sup> 35,000, CREON<sup>®</sup> 40,000

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## 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.

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### 1. Why am I using CREON?

CREON contains the active ingredient Pancreatic extract. CREON 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?](#) in the full CMI.

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

Do not use if you have ever had an allergic reaction to CREON 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?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with CREON 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?**

- Your doctor will tell you how many capsules to take to suit your particular needs. Do not increase the number of capsules yourself without informing your doctor.
- Swallow the capsules whole with a full glass of water or, if you prefer, open the capsules and mix the granules with soft food.

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

### **5. What should I know while using CREON?**

<b>Things you should do</b>	
	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using CREON.</li></ul>

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

store CREON capsules in the refrigerator.

- After opening use within 6 months.

For more information, see Section [5. What should I know while using CREON?](#) 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<sup>®</sup> 10,000, CREON<sup>®</sup> 25,000, CREON<sup>®</sup> 35,000, CREON<sup>®</sup> 40,000

Active ingredient(s): *Pancreatic extract*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using CREON 10,000, CREON 25,000, CREON 35,000 and CREON 40,000. **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. Please read this leaflet before you start taking CREON capsules.** If you are helping someone else to take Creon capsules, please read this leaflet before you give the first dose.

### Where to find information in this leaflet:

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

## **1. Why am I using CREON?**

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

**CREON 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 capsules are 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.**

**CREON 25,000, CREON 35,000 and CREON 40,000 cannot be obtained without a doctor's prescription.**

**There is no evidence that CREON capsules are addictive.**

## **2. What should I know before I use CREON?**

### **Warnings**

#### **Do not use CREON 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, or if the capsules do not look quite right.
- 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 these products.

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

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 and affect how it works.**

You should avoid taking antacids, which are medicines that are used to treat heartburn and indigestion, when taking CREON capsules. Antacids may affect how well CREON capsules 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 capsules.



**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.**

## **4. How do I use CREON?**

### **How much to take**

- Follow all directions given to you by your doctor carefully.
- Your doctor will tell you how many capsules to take to suit your particular needs. Do not increase the number of capsules yourself without informing your doctor.
- For children and adolescents with cystic fibrosis, your doctor will have determined a dose specific to the patient's body weight and condition.
- For adult patients starting CREON for the first time, the usual starting dose is 25 000 to 40 000 units of lipase with each meal and half this dose with snacks. Your doctor may need to make a number of adjustments before determining the right dose which suits you best. If needed, the dose can be increased up to 80,000 units of lipase with each meal.
- It is normally not necessary to restrict your diet of fat while you are taking CREON 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.
- If the doctor advises you to increase the dosage, you should increase the number of capsules gradually

(for example, by one at a time). 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.

- 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 and use CREON until your doctor tells you to stop.

## **When to take**

- Take CREON capsules with every meal and snack.

## **How to take CREON**

- Swallow the capsules whole with a full glass of water or, if you prefer, open the capsules and mix the granules with soft food.
- If you mix the granules with food, it is important to swallow the mixture straight away, without chewing.
- Neither the capsules nor the granules inside should be chewed as they have a special coating to stop them dissolving until they have gone through the stomach and into the intestines where they work.
- When you are taking CREON capsules, it is important to make sure that you drink plenty of liquid every day.

## **If you forget to use CREON**

CREON 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 capsules.

**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**

If you think that you have used too much CREON, 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?**

### **Things you should do**

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

**Follow your doctor's instructions carefully and do not stop taking the capsules unless told to do so by your doctor.**

### **Call your doctor straight away if you:**

- are still having problems with fatty stools or abdominal pain while you are taking CREON capsules.

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

### **Things you should not do**

- Do not give CREON capsules 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

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

## Drinking alcohol

**Tell your doctor if you drink alcohol.**

## Looking after your medicine

- Keep your capsules in the bottle until it is time to take them.
- If you take the capsules out of the bottle they may not keep well.
- **Keep your CREON capsules 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 capsules in the refrigerator. After opening use within 6 months.**

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

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

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 (as relevant)**

**After opening use within 6 months.**

**If your doctor tells you to stop taking CREON capsules, or the capsules have passed their expiry date, ask your pharmacist what to do with any that are left over.**

## **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
<p><b>Stomach or bowel problems, including:</b></p> <ul style="list-style-type: none"> <li>• diarrhoea</li> <li>• constipation</li> <li>• abnormal stools</li> <li>• abdominal discomfort</li> <li>• nausea</li> </ul> <p>Skin reactions</p>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p> <p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<p><b>Severe or prolonged abdominal pain</b></p> <p><b>Narrowing of the bowel</b></p> <ul style="list-style-type: none"> <li>• Several children with cystic fibrosis who were taking high doses of pancreatic enzyme</li> </ul>	<p><b>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.</b></p> <p><b>Call your doctor straight away, or go straight to the Emergency Department at your</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>supplements have suffered from narrowing of the bowel and required an operation.</p> <ul style="list-style-type: none"> <li>●</li> <li>●</li> <li>●</li> <li>●</li> <li>●</li> <li>● <b>High levels of uric acid in their blood and urine</b></li> <li>● In rare cases, people taking very high doses have had a tendency to develop high levels of uric acid in their blood and urine.</li> <li>●</li> <li>● <b>Irritation or inflammation in the anal region</b></li> <li>● If you take too much Creon you may get irritation or inflammation in the anal region..</li> </ul>	<p><b>nearest hospital if you notice any of these serious side effects.</b></p> <p><b>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.</b></p> <p><b>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.</b></p>

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



The active ingredient in CREON capsules 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](http://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 contains

<b>Active ingredient (main ingredient)</b>	<p>CREON 10,000 - Pancreatin Extract 150 mg equivalent to not less than lipase 10,000 Ph.Eur. units, amylase 8,000 Ph.Eur. units and protease 600 Ph. Eur. units.</p> <p>CREON 25,000 - Pancreatic Extract 300 mg equivalent to not less than lipase 25,000 Ph.Eur. units, amylase 18,000 Ph.Eur. units and protease 1,000 Ph. Eur. units.</p> <p>CREON 35,000 - Pancreatic Extract 420 mg equivalent to not less than lipase 35,000 Ph.Eur. units, amylase 25,200 Ph.Eur. units and protease 1,400 Ph. Eur. units.</p> <p>CREON 40,000 capsule contains Pancreatic Extract 400mg equivalent to not less than lipase 40,000 Ph.Eur. units, amylase 25,000 Ph.Eur.</p>
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	units and protease 1,600 Ph. Eur. units.
<b>Other ingredients (inactive ingredients)</b>	<p>macrogol 4000</p> <p>hypromellose phthalate</p> <p>cetyl alcohol</p> <p>triethyl citrate</p> <p>dimeticone 1000</p> <p>gelatin</p> <p>titanium dioxide</p> <p>sodium lauryl sulfate</p> <p>iron oxide red (only present in CREON 10,000 &amp; CREON 25,000 &amp; CREON 35,000)</p> <p>iron oxide black (only present in CREON 10,000 &amp; CREON 35,000)</p> <p>iron oxide yellow (only present in CREON 10,000 &amp; CREON 25,000 &amp; CREON 35,000)</p> <p>iron oxide (only present in CREON 40,000)</p>
<b>Potential allergens</b>	sulfites

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

## **What CREON looks like**

CREON 10,000 is a dark brown/colourless capsule containing small brownish coloured granules (minimicrospheres) that have a special coating. Available in bottles of 100 capsules (AUST R 158453).

CREON 25,000 is a light brown/colourless capsule containing small brownish coloured granules (minimicrospheres) that have a special coating. Available in bottles of 100 capsules (AUST R 158452).

CREON 35,000 is a red brown/colourless capsule containing small brownish coloured granules (minimicrospheres) that have a special coating. Available in bottles of 100 capsules (AUST R 313833).

CREON 40,000 is an opaque brown/colourless-transparent capsule containing brownish minimicrospheres in bottles of 100 capsules (AUST R 158451).

## **Who distributes CREON**

Viatrix Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatrix.com.au](http://www.viatrix.com.au)

Phone: 1800 274 276

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