PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S1**

CREON 25 000 hard capsules

Lipase 25 000 Ph. Eur. units

Amylase 18 000 Ph. Eur. units

Protease 1 000 Ph. Eur. units.

Sugar free.

Read all of this leaflet carefully because it contains important information for you

CREON is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use CREON carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share CREON with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet

1. What CREON is and what it is used for
2. What you need to know before you take CREON
3. How to take CREON
4. Possible side effects

5. How to store CREON

6. Contents of the pack and other information.

1. What CREON is and what it is used for

CREON contains an enzyme mixture called pancreas powder.

Pancreas powder aids digestion. The enzymes are obtained from porcine pancreas.

CREON capsules contain gastro-resistant pellets that slowly release the pancreas powder in the intestine.

2. What you need to know before you take CREON

Do not take CREON

- If you are hypersensitive (allergic) to porcine pancreatin (pancreatin derived from pig) or to any of the other ingredients of CREON (listed in section 6).
- If you have early stages of acute pancreatitis (a condition where your pancreas becomes inflamed (swollen) over a short period of time, due to the fact that you are not allowed to eat for the first two to three days).

Warnings and precautions

Take special care with CREON:

Strictures of the large bowel have been reported in patients with cystic fibrosis taking high doses of pancreatin preparations.

If you suffer from cystic fibrosis and take in excess of 10 000 units of lipase per kg per day and experience unusual abdominal symptoms or changes in abdominal symptoms please tell your doctor.

CREON comes from pancreatic tissue derived from swine especially bred for food consumption. Although the risk that CREON will transmit an infectious agent to humans has been reduced by the testing and inactivation of certain viruses during manufacturing, there is a theoretical risk for transmission of a viral disease, including diseases caused by novel or unidentified viruses. The presence of porcine viruses that might infect humans cannot be definitely excluded. However, no cases of transmission of an infectious illness associated with the use of porcine pancreatic extracts have been reported, whereas they have been used for a long time.

This medicine contains less than 1 mmol sodium (23 mg) per capsule, i.e. it is virtually "sodium-free".

Other medicines and CREON

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)
No interaction studies between CREON have been performed.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking CREON.

Safety of CREON in pregnancy has not been established. CREON should not be used during pregnancy or breastfeeding.

Driving and using machines

No effects on the ability to drive a vehicle or use machines are anticipated.

3. How to take CREON

Do not share medicines prescribed for you with any other person.

Always take CREON exactly as your doctor has instructed you. If you have any questions, contact your doctor or pharmacist.

The usual dose recommended for children, adolescents and adults with cystic fibrosis is based on weight:

- It will begin with 1 000 lipase units per kg per meal for children less than four years of age and with 500 lipase units per kg per meal for those patients over the age of four.
- Your doctor will adjust the dosage according to the severity of the disease, control of steatorrhoea (fatty stools) and maintenance of good nutritional status.
- For most patients a dose of 10 000 lipase units per kg body weight per day or 4000 lipase units per gram fat intake will suffice.

In other conditions associated with exocrine pancreatic insufficiency:

- Your individual dosage will be determined according to the degree of disturbed digestion and the fat content of the meal. The required dose for a meal ranges from about 25 000 to 80 000 units of lipase and half of the individual dose for snacks.

Always follow your doctor's advice on how much CREON to take. Your doctor will adjust your dose to your individual needs.

If you still have fatty stools or other gastrointestinal symptoms, talk to your doctor.

Always take CREON during or after a meal or a snack and drink plenty of water. Swallow the capsules whole without crushing or chewing. When swallowing of capsules is difficult (for instance in small children or elderly patients), you may open the capsules carefully and add the gastro-resistant pellets to small amounts of soft acidic food, such as apple sauce, mashed

bananas or carrots or you can take them with liquid. Swallow the CREON soft food mixture immediately without crushing or chewing and drink some water or juice.

It is important to ensure adequate hydration at all times, especially during periods of increased loss of fluids (e.g. diarrhoea and vomiting). Inadequate hydration may aggravate constipation.

Drink plenty of liquid every day.

If you take more CREON than you should

If you take more than your normal dose, contact your doctor or nearest hospital immediately. In the event of overdosage, consult your doctor or pharmacist.

If neither is available, seek help at the nearest hospital or poison control center.

If you forget to take a dose of CREON

If you forget to take your medicine, wait until your next meal and take your usual dose. Do not try to make up for the dose that you have missed. You should take your medicines until your doctor tells you to stop. Many patients will need to take pancreatic enzymes supplements for the rest of their lives.

Do not stop taking CREON without first talking to your doctor.

4. Possible side effects

CREON can have side effects.

Not all side effects reported for CREON are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CREON, please consult your health care provider for advice.

If any of the following happens, stop taking CREON and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching, urticaria (hives)
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to CREON. You may need urgent medical attention or hospitalisation.

Tell your doctor as soon as possible if you notice any of the following:

Frequent side effects

- stomach pain
- nausea (feeling sick), vomiting (being sick)
- constipation
- abdominal distention (bloating)
- satiety (state of fullness)
- diarrhoea.

Less frequent side effects

- abnormal stool
- soreness around the area of the anus and mouth (oral and peri-anal soreness)
- hyperuricosuria (excessive uric acid in urine) and hyperuricaemia (excessive uric acid in the blood) with high doses.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of CREON.

5. How to store CREON

Store all medicines out of reach of children.

Store at or below 25 °C in protected from light.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CREON contains

The active substance is porcine pancreas powder with lipase, amylase and protease activity.

Each hard capsule contains gastro-resistant pellets of 300 mg pancreatin, produced from porcine pancreatic tissue, equivalent to

	(Activities in European Pharmacopoeia units)
Lipase	25 000 Ph. Eur. units
Amylase	18 000 Ph. Eur. units
Protease	1 000 Ph. Eur. units.

The other ingredients are cetyl alcohol, triethyl citrate, dimethicone 1 000, macrogol 4 000, hypromellose phthalate, gelatine, sodium laurilsulfate, titanium dioxide (E171) and iron oxides (E172).

What CREON looks like and contents of the pack

Hard gelatin capsule (size 2) with a brown opaque top half and a colourless transparent bottom half, filled with brownish pellets.

White high-density polyethylene (HDPE) containers with tamper evident polypropylene (PP) screw caps, packed in carton boxes in packs of 100, 150 or 300 capsules or
Aluminium-aluminium blister strips, packed in carton boxes in packs 20, 50 or 100 capsules.
Not all pack sizes may be marketed.

Holder of Certificate of Registration

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