

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

CREON 25,000

Capsules

Each capsule contains: Pancreatin 300 mg, comprising:

Lipase 25,000 Ph. Eur. Units
Amylase 18,000 Ph. Eur. Units
Protease 1,000 Ph. Eur. Units

For a list of the inactive ingredients in the medicine, see section 6.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

- Creon 25,000 is a high-dosage pancreatic enzyme supplement indicated for people whose bodies cannot produce enough enzymes required to digest food.
- The capsules contain a mix of natural enzymes used to digest food.
- The enzymes are extracted from pig pancreas.
- The medicine should be taken as per the doctor's instructions.
- Take the medicine together with a meal or snack, with a lot of water (see section 3).
- Do not take the medicine if you are allergic to pig-derived ingredients, pig proteins (see section 2).
- If you experience **severe abdominal pains** during the course of treatment with the medicine, refer to the doctor immediately (see section 4).

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended to treat exocrine pancreatic insufficiency.

The medicine contains pancreatic enzymes which aid digestion, in cases where the pancreas does not produce these enzymes, or does not produce enough of them. The medicine is intended to balance low enzymatic activity in the intestine, in

cases of pancreatic insufficiency, e.g., cystic fibrosis, chronic pancreatitis, excision of the pancreas and partial excision of the digestive system in adults and children.

Therapeutic group: Digestive enzymes.

2. BEFORE USING THE MEDICINE

X Do not use the medicine if:

you are sensitive (allergic) to the active ingredient, pancreatin of porcine origin, to products of pig origin, pig proteins or to any of the additional ingredients contained in the medicine (see section 6).

If this section applies to you, do not take the medicine. Consult with the doctor again.

Special warnings regarding use of this medicine

X Before using the medicine, inform the doctor if you are sensitive to any food or medicine.

X Additional warnings

A rare bowel condition called fibrosing colonopathy (narrowing of the large intestine) has been reported in patients with cystic fibrosis taking high dosages of preparations containing pancreatin.

If you have cystic fibrosis and take doses higher than 10,000 lipase units per kilogram body weight per day, **refer to a doctor** if you have unusual abdominal symptoms or changes in regular abdominal symptoms.

X If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

X Use of the medicine and food

The digestive enzymes in the medicine act when food is passing through the intestine, and therefore, the medicine should be taken with a meal or snack. This will allow the enzymes to effectively mix with the food (see section 3).

X Pregnancy and breastfeeding

If you are pregnant or trying to become pregnant, consult the doctor or pharmacist before using the medicine. This medicine can be used when breastfeeding.

X Driving and use of machinery

It is unlikely that the medicine will affect your ability to drive or operate dangerous machinery.

X Important information regarding some of the ingredients in the medicine

The amount of sodium in each capsule: 3.9 mg.

This medicine does not contain sugar or lactose.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain.

The dosage and treatment regimen will be determined by the doctor only.

If the doctor has told you to increase the dose (to increase the number of capsules), do so gradually. If you still have fatty stools or abdominal pains, inform the doctor.

Do not exceed the recommended dose.

Take the medicine during or immediately after a meal or a snack.

Swallow the medicine with a lot of water.

Do not chew or crush the medicine, so as not to destroy the inner coating, within which the enzymes are enclosed, thereby abolishing the enzymatic activity of the medicine.

How should the medicine be taken

Swallow the capsule whole, or, if you have a hard time swallowing whole capsules, the capsule can be carefully opened and its contents can be mixed (without mashing) with an acidic liquid (e.g., apple, orange or pineapple juice) or with a soft acidic food (e.g., apple sauce or yogurt). If the contents of the capsule are mixed with food or a beverage, take the mixture immediately, without mashing or chewing, so that the inner coating will not dissolve. Do not store the mixture.

Note:

Be sure to maintain adequate fluid intake at all times during the course of treatment with the medicine, especially when there is increased fluid loss (e.g., vomiting and diarrhea). Failure to drink adequately may worsen constipation. It is important to drink a lot every day!

Mashing/chewing the granules in the capsule or mixing the contents of the capsule with food or a nonacidic beverage may cause irritation in the mouth or change the way Creon works in the body.

Do not hold the whole capsule or mixture in the mouth for more than the time necessary to swallow it.

- The bottle is closed with a child-proof cap. Press down and turn to open it.

- Child-proof caps have significantly lowered the number of poisoning incidents caused by medicines each year. However, if you are having a hard time opening the package, you can refer to a pharmacist to have the safety mechanism removed from the cap and to turn it into a regular, easy-to-open cap.

- The capsule can be opened and its contents dispersed.
- Do not crush, mash or chew the medicine.
- Duration of treatment - continue taking the medicine until your doctor tells you to stop. Many patients need to take pancreatic enzyme supplements throughout their lifetime.

If you accidentally took a higher dosage, drink lots of water. If you took an overdose, or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

If you forgot to take this medicine at the required time, do not take a double dose to compensate for the forgotten dose. Take the next dose with the next meal.

Adhere to the treatment regimen recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine, without consulting with the doctor or pharmacist.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Creon 25,000 may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

If you have severe and long-lasting abdominal pains or abnormal abdominal symptoms, consult with the doctor immediately.

The following side effects were reported in clinical trials conducted among more than 900 patients who took Creon: Side effects occurring very frequently (affect more than 1 in 10 users):

- stomach pains

Side effects occurring frequently (affect 1-10 in 100 users):

- diarrhea
- constipation
- nausea or vomiting
- bloating

Side effects occurring infrequently (affect 1-10 in 1,000 users):

- Skin reactions, such as a rash

During use, some patients have also experienced the following effects, the frequency of which is unknown:

- itching with or without a rash
- allergic reactions (which may be severe, such as breathing difficulties or swelling of the lips)
- severe or long-lasting abdominal pains (fibrosing colonopathy)

Severe or long-lasting abdominal pains caused by narrowing of the large intestine (fibrosing colonopathy) have been reported in cystic fibrosis patients taking preparations containing high dosages of pancreatin.

Very high dosages of pancreatin have sometimes caused high levels of uric acid in the blood and urine.

If a side effect occurs, if any of the side effects worsen or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health via the online form in the following link:

<http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic%40moh.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Do not store at a temperature that exceeds 25°C. Close tightly to prevent penetration of air and moisture. Store in the original package.
- Can be used for 3 months from the time the bottle is first opened.

- The enzymes in the medicine are natural enzymes, whose capacity to digest food declines with time. If the medicine is stored in hot temperatures (e.g., the glove box in the car), the digestive capacities of the enzymes in the medicine will decline faster.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains -

Hypromellose phthalate, Macrogol 4,000, Triethyl citrate, Dimeticone 1,000, Cetyl alcohol.

Capsule: Gelatine, Iron oxides (red, yellow) (E172), Sodium lauryl sulphate, Titanium dioxide (E171).

Each capsule contains 3.9 mg sodium

- What the medicine looks like and the contents of the package - the medicine is composed of brownish granules in hard gelatin capsules.

The medicine is marketed in a carton box that contains a bottle with a child-safety cap.

Package sizes - 100 capsules, 50 capsules.

Not all package sizes are marketed.

- Registration holder and address: Abbott Medical Laboratories Ltd., Kiryat Atidim P.O.B. 58099, Tel-Aviv.

- Manufacturer: Abbott Laboratories GmbH, Hanover, Germany.

- This leaflet was checked and approved by the Ministry of Health in June 2015.

- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 119-75-29972-00.