

PATIENT INFORMATION LEAFLET

PANCREASE™ CAPSULES

Before you start to use your medicine, please read this leaflet carefully all the way through as it contains important information. It does not contain the complete information about this medicine. If there is anything that you do not understand or if you need further information or advice, you should ask your pharmacist or doctor who will have more details.

This leaflet applies only to Pancrease Capsules. Please do not throw it away as you may need to refer to it again.

WHAT IS YOUR MEDICINE?



The name of your medicine is Pancrease Capsules. Each capsule contains not less than:

Protease	330 BP units
Amylase	2900 BP units
Lipase	5000 BP units

- **Other ingredients**

Non pareil seeds, povidone, sodium starch glycolate, cellulose acetate phthalate, diethyl phthalate and talc.

- **What should your medicine look like?**

White opaque gelatin capsule with 0095 printed on the body of the capsule. Each capsule contains a number of off-white coloured microspheres. Pancrease Capsules come in a polyethylene bottle containing 100 capsules.

- **What type of medicine is Pancrease?**

Pancrease is a pancreatic enzyme replacement therapy and replaces the three enzymes lipase, amylase and protease which your pancreas is not able to produce.

- **Product Licence holder**

Janssen-Cilag Ltd
Saunderton
High Wycombe
Buckinghamshire

HP14 4HJ
UK

- **Manufactured by**

McNeil Pharmaceutical
Spring House
Fort Washington
Pennsylvania 19477
USA

WHAT IS YOUR MEDICINE USED FOR?



Pancrease Capsules are used to replace the enzymes which are lacking when the pancreas is not able to produce them itself. These enzymes are called protease, amylase and lipase and they help break down and digest the food that you eat. Without them your body will not receive the nourishment it needs. If you have/have had any of the following it is likely that you will not be able to produce these enzymes properly yourself.

- cystic fibrosis;
- chronic pancreatitis;
- blockage of the pancreas or bile ducts;
- surgery to remove the pancreas or to bypass the stomach.

REMEMBER - This medicine is for you only. Never give it to anyone else. It may harm them even if their symptoms are the same as yours.

WHEN NOT TO USE YOUR MEDICINE



Do not use Pancrease Capsules if:

You have ever experienced an allergic reaction (hypersensitivity) to pork protein or to any of the other ingredients in this medicine.

Inform your doctor before taking this medicine if any of the above applies to you. Your doctor will then decide whether Pancrease Capsules are suitable for you.

SPECIAL PRECAUTIONS

Contact of the microspheres with food which is neutral or alkaline (pH higher than 5.5, eg milk, custard, ice cream and other dairy products) can dissolve the

protective coating and will affect the way in which this product will work inside your body.

- **Pregnancy**



Do not use Pancrease Capsules if you are pregnant, or think you may be pregnant.

- **Other medicines**



You can take Pancrease Capsules if you are also taking other medicines, but do remember to tell your doctor if you are taking any that he may not know about.

HOW TO USE YOUR MEDICINE



Pancrease Capsules should be taken by mouth during each meal or snack.

HOW MUCH SHOULD YOU TAKE?

Your doctor will discuss with you how many capsules you should take; this is usually one or two at a time, but may be more. The number of capsules you will need to take will depend on your symptoms, how well you respond to the capsules, and also on what you are eating.

- Do not take the capsules on an empty stomach as they will not have any useful effect.
- Do not chew or crush the capsules as this will damage the microspheres inside so that the medicine will not work properly.
- If you have difficulty swallowing the capsules, you may open them and mix the microspheres inside with any food or drink that you are eating which does not need to be chewed. This will not affect the taste of the food.
- You should carry on taking Pancrease Capsules as long as your doctor tells you to. Do not stop taking them without talking to your doctor about doing so.

IF YOU FORGET TO TAKE YOUR MEDICINE

If you forget to take the capsules with any meal or snack just carry on taking them as normal when you next have something to eat.

IF YOU TAKE TOO MUCH OF YOUR MEDICINE



It is unlikely that you will suffer any serious effects if you take too many Pancrease Capsules, but if you do take a large number by accident you may experience stomach pain, nausea, vomiting and soreness/itching of your bottom. Contact your doctor for advice.

IF YOU THINK YOUR MEDICINE MAKES YOU FEEL ILL



As with other medicines, Pancrease Capsules may cause some unwanted effects. Most of these are usually minor and include:

- Stomach pains;
- Nausea;
- Vomiting;
- Very high doses of Pancrease have been known to cause high levels of uric acid in the blood and urine;
- Allergic reactions;
- Allergic skin reactions.

If you experience any of these effects, or any other which you think may be due to the medicine, then please contact your doctor.

HOW TO STORE YOUR MEDICINE



Pancrease Capsules should be stored at room temperature in a dry place. Keep the bottle tightly closed. Do not refrigerate. Do not use the medicine after the expiry date printed on the packaging and return any left over medicine to your pharmacist.

Date of revision of leaflet: 18 May 2000

© Janssen-Cilag Ltd
Saunderton
High Wycombe
Buckinghamshire
HP14 4HJ
UK

™ trademark