

PATIENT INFORMATION LEAFLET

PANCREASE™ HL CAPSULES (pancreatin equivalent to pancrelipase)

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 HL 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 HL Capsules. Each capsule contains not less than:

Protease	1250 units
Amylase	22500 units
Lipase	25000 units

- **Other ingredients**

Minitablet: castor oil, silicon dioxide, magnesium stearate, sodium carboxymethylcellulose, microcrystalline cellulose.

Minitablet coating: simethicone emulsion, methacrylic acid copolymer, talc, triethyl citrate, water.

Capsule (body and cap): titanium dioxide, gelatin.

Ink: Shellac, methylated spirits, water, soya lecithin, 2-ethoxyethanol, dimethylpolysiloxane, red iron oxide (E172).

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

White opaque gelatin capsule, ringed with a red band and the letters HL in red. Each capsule contains a number of light brown coloured minitables.

Pancrease HL Capsules come in a polyethylene bottle containing 100 or 500 capsules.

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

Pancrease HL 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**

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WHAT IS YOUR MEDICINE USED FOR?



Pancrease HL 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 HL Capsules if:

- you have ever experienced an allergic reaction (hypersensitivity) to pork protein or to any of the other ingredients in this medicine.
- you are aged 15 years or under and have cystic fibrosis.

If you develop severe stomach pains and vomiting, please see your doctor.

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

SPECIAL PRECAUTIONS

Contact of the minitablets with food which is neutral or alkaline (pH higher than 5.5) can dissolve the protective coating and will affect the way in which this product will work inside your body.

- **Pregnancy**



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

- **Other medicines**



You can take Pancrease HL 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 HL 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 minitablets inside so that the medicine will not work properly.

- If you have difficulty swallowing the capsules, you may open them and mix the minitablets 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.
- It is important that you drink plenty of water while you are taking Pancrease HL Capsules.
- Some patients who are given more than 10,000 units of lipase per kilogram per day, which is more than your doctor will normally prescribe, have developed damage to their bowel. However, the amount of Pancrease HL prescribed for you by your doctor should not usually be as high as this.
- You should carry on taking Pancrease HL 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 HL 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 HL Capsules may cause some unwanted effects. Most of these are usually minor and include:

- Stomach pains;
- Nausea;
- Vomiting;
- Allergic reactions;
- Allergic skin reactions.


Very high doses of Pancrease have been known to cause high levels of uric acid in the blood and urine.

In children with cystic fibrosis, and who are taking Pancrease HL, narrowing or inflammation of the bowel has been reported.

If you experience stomach pains, or any change in stomach pains, you should contact your doctor, who will check that no damage has been caused to your intestine.

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 HL Capsules should be stored at room temperature (between 10°C and 25°C), in a dry place, where children cannot reach them. Keep the bottle tightly closed. Do not refrigerate. Do not use your medicine after the expiry date printed on the label.

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