

## PACKAGE LEAFLET: INFORMATION FOR THE USER

# Pancrease™ HL

Pancreatin equivalent to pancrelipase

Pancrease is a trademark

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
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### What is in this leaflet

1. What Pancrease HL is and what it is used for
2. What you need to know before you take Pancrease HL
3. How to take Pancrease HL
4. Possible side effects
5. How to store Pancrease HL
6. Contents of the pack and other information

## 1. What Pancrease HL is and what it is used for

Pancrease HL is a white capsule that contains light brown coloured mini-tablets. It belongs to a group of medicines called 'pancreatic enzyme replacement therapy'. Pancrease HL contains three medicines:

- Protease
- Amylase
- Lipase

They are proteins (called enzymes) that help you to break down and digest food. Without them your body will not receive the nourishment it needs.

It may be necessary to take Pancrease HL if you have or have had any of the following:

- Cystic fibrosis (a problem with your digestive system and lungs)
- Long-term inflammation of your pancreas (chronic pancreatitis). The pancreas is a gland behind your stomach
- Blockage of your pancreas or passage (duct) that releases 'bile'. Bile is a fluid made by the liver
- Surgery to remove your pancreas or bypass your stomach

## **2. What you need to know before you take Pancrease HL**

### **Do not take Pancrease HL:**

- If you are under 15 years old and have cystic fibrosis

### **Warnings and precautions**

Check with your doctor or pharmacist before taking this medicine:

- If you have had an allergic reaction to pork protein or any of the other ingredients of this medicine (listed in Section 6).
- If you have gout (a disease with painful, swollen joints caused by uric acid crystals) or kidney problems as Pancrease HL can increase the levels of uric acid

### **Other medicines and Pancrease HL**

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. This includes medicines that you buy without a prescription or herbal medicines. You may still be able to take Pancrease HL if you are taking other medicines.

### **Pancrease HL with food and drink**

- You will need to drink plenty of water every day while taking Pancrease HL
- If you have difficulty swallowing the capsules, you can open them and mix the mini-tablets inside with drinks or soft foods that don't need to be chewed. It will not affect the taste of the food
- If you need to mix the mini-tablets with food or drink, please ask your doctor for advice on the best food or drink to use. Pancrease HL will not work as well if they are mixed with certain foods (such as milk, custard, ice cream, and many other dairy products)

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You may still be able to use Pancrease HL if your doctor thinks you need to.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

### **Driving and using machines**

This medicine is unlikely to affect you being able to drive or use any tools or machines.

This medicine contains less than 1 mmol sodium (23 mg) per capsule that is to say essentially 'sodium-free'.

### **3. How to take Pancrease HL**

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

#### **How many capsules to take**

Your doctor will tell you how many capsules you should take. The recommended dose is 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 the medicine works for you
- What you eat

#### **How to take Pancrease HL**

- You will need to drink plenty of water every day while taking Pancrease HL
- The capsules should be taken by mouth with each meal or snack
- If you have difficulty swallowing the capsules, you can open them and mix the mini-tablets inside with drinks or soft foods that don't need to be chewed. It will not affect the taste of the food
- If you need to mix the mini-tablets with food or drink, please ask your doctor for advice on the best food or drink to use. Pancrease HL will not work as well if they are mixed with certain foods (such as milk, custard, ice cream, and many other dairy products)

#### **It is important that you:**

- Do not chew or crush the capsules as this will damage the mini-tablets inside. This will stop the medicine working properly
- Do not take the capsules (or mini-tablets inside) on an empty stomach as they will not have any effect

#### **If you take more Pancrease HL than you should**

If you take a lot of capsules by accident you might:

- Feel sick (nausea), be sick (vomit) or have stomach pain

- Have a sore or itchy bottom

If this happens, contact your doctor as soon as possible.

#### **If you forget to take Pancrease HL**

- If you forget to take your capsules, take them as soon as you remember. However, if it is nearly time for the next capsules, skip the missed capsules
- Do not take a double dose to make up for a forgotten dose

#### **If you stop taking Pancrease HL**

- Keep taking Pancrease HL as long as your doctor tells you to. Do not stop taking it without talking to your doctor first.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Stop using Pancrease HL and tell your doctor straight away if you notice the following. You may need medical treatment.**

- Severe irritation or reddening of your skin or other signs of allergy during treatment. This only happens in a small number of people taking other pancreatic enzyme products. It has not been reported in patients taking Pancrease HL.

**Contact your doctor as soon as possible if:**

- You get an obstruction of the intestine and severe or long lasting stomach pains, unusual stomach pains or a change in existing stomach pain (Fibrosing colonopathy). Other signs include constipation, diarrhoea, bloated stomach and being sick (vomiting). Your doctor will check that no damage has been caused to your gut (intestine).

#### **Other side effects**

##### **Very common (can affect more than 1 in 10 people)**

- Stomach pain

##### **Common (affects less than 1 in 10 people)**

- Rash
- Bloated stomach, diarrhoea, feeling sick (nausea) and being sick (vomiting)

##### **Not known (frequency cannot be estimated from the available data)**

- Constipation

## Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Pancrease HL

Keep this medicine out of the sight and reach of children.

- Keep the bottle tightly closed
- Do not store above 25°C
- Do not refrigerate or freeze

Do not use Pancrease HL after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What Pancrease HL contains

**The active substances** are:

- Protease (not less than 1,250 units)
- Amylase (not less than 22,500 units)
- Lipase (not less than 25,000 units)

**The other ingredients** are

**Mini-tablet:** hydrogenated castor oil, silica colloidal anhydrous, magnesium stearate, croscarmellose sodium, microcrystalline cellulose

**Mini-tablet coating:** simethicone emulsion, methacrylic acid-ethyl acrylate copolymer (1:1), talc, triethyl citrate, water

**Capsule (body and cap):** titanium dioxide, gelatine

**Ink:** Shellac, red iron oxide (E172), dehydrated alcohol, strong ammonia solution, propylene glycol, isopropyl alcohol, butyl alcohol.

OR

**Ink:** Shellac, red iron oxide (E172), dehydrated alcohol, propylene glycol, isopropyl alcohol, butyl alcohol, strong ammonia solution, potassium hydroxide, water

**What Pancrease HL looks like and contents of the pack**

Pancrease HL is an opaque gelatine capsule, ringed with a red band and the letters HL in red. Each capsule contains a number of light brown mini-tablets. Pancrease HL capsules come in a polyethylene bottle containing 100 or 500 capsules.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder:**

JANSSEN-CILAG LTD, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG.

**Manufacturer:**

Lusomedicamenta Sociedade Technica Farmaceutica SA, Estrada Consiglieri Pedroso, 69B, Queluz de Baixo, 2730-055 Barcarena, Portugal

Or

McGregor Cory Ltd, Middleton Close, Banbury, Oxfordshire, OX16 4RS, UK

**For information in large print, tape, CD or Braille, telephone 0800 7318450.**

This leaflet was last revised in February 2020.