

Package leaflet: Information for the user
Pancrex V 340 mg hard capsules

pancreatin

The full name of this medicine is “Pancrex V 340 mg hard capsules”. The short form of the name “Pancrex V” is used throughout the remainder of the package leaflet.

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

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

1. What Pancrex V is and what it is used for

Pancrex V contains the active substance pancreatin.

Pancreatin is a combination of enzymes normally produced by the pancreas which help to digest protein, fat, starch and sugars in the food that you eat.

Pancreatin is given to people who do not produce enough enzymes to digest their food properly, in conditions such as cystic fibrosis, persistent inflammation of the pancreas, and when the pancreas has been removed. Pancrex V may also be used when the stomach has been removed, as an aid to digestion.

These capsules may be used when small amounts of pancreatin are required, such as in younger children. The capsules may also be used in patients who cannot easily dissolve the special coating of other pancreatin preparations.

The pancreatin in Pancrex V is derived from pancreases of pigs.

2. What you need to know before you take Pancrex V

Do not take Pancrex V

- If you are allergic to pancreatin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Pancrex V.

Some irritation of the skin of the mouth may occur if the capsules are chewed or the contents kept in the mouth. Irritation of the anus may also occur, which may be prevented by use of a barrier cream.

It is possible that some people may be allergic to Pancrex V. Allergic/asthmatic reactions have occasionally occurred on handling the capsule contents.

Signs of an allergy to something include rash, wheezing, breathlessness, swollen eyelids, face or lips, and in extreme cases collapse. In the unlikely event that you should get any of these symptoms soon after taking Pancrex V, do not take any more. **Tell a doctor straight away and take the packaging and this leaflet with you.**

Other medicines and Pancrex V

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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 as dose adjustments may be necessary.

Driving and using machines

Pancrex V does not interfere with your ability to drive or operate machinery.

3. How to take Pancrex V

Dosage

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Your doctor or pharmacist will advise you on the amount of Pancrex V to take before each meal, although you may find with experience that you need to adjust the dose according to the size and type of meal that you eat. If loose pale stools (faeces) occur you may need to increase the dose.

The following should provide a good starting point for adjustment of the dose:

- For infants, the contents of 1-2 capsules mixed with feeds.
- For older children and adults, 2-6 capsules (or their contents) with each meal or snack.

If the capsule contents are mixed with liquids or feeds, use within one hour.

If you take more Pancrex V than you should

There are no special precautions to take.

If you forget to take Pancrex V

Simply skip that dose and take the next dose with your next meal or snack. Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

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

Rarely, high levels of uric acid in the blood and urine have been reported when extremely high doses of pancreatin have been taken.

Narrowing of parts of the bowel, and inflammation of the colon, have been reported in children with cystic fibrosis taking high doses of pancreatic enzyme supplements.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Pancrex V

Store in a refrigerator (2°C - 8°C).

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

Do not use this medicine after the expiry date which is stated on the label after EXP. 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 Pancrex V contains

The active substance is pancreatin. Each capsule contains at least:

- 430 BP units of free protease, an enzyme that digests protein
- 8000 BP units of lipase, an enzyme that digests fat
- 9000 BP units of amylase, an enzyme that digests starch and sugars

BP is a British standard measure of potency (expected biological effect) of a pharmaceutical product.

The other excipients are aluminium oxide, magnesium stearate, microcrystalline cellulose, titanium dioxide (E171), yellow iron oxide (E172) and quinoline yellow (E104).

The capsule is made of gelatin, which is of bovine origin.

What Pancrex V looks like and contents of the pack

Pancrex V consists of white or buff-coloured powder in an ivory-coloured hard gelatin capsule imprinted with 'Pancrex V' and a company logo.

Each plastic container holds 100, 300 or 500 capsules.

However, not all pack sizes may be marketed.

Marketing Authorisation Holder

Essential Pharmaceuticals Ltd, 8a Crabtree Road, Egham, Surrey, TW20 8RN, UK.

Manufacturer

Lelypharma B.V., Zuiveringweg 42, 8243 PZ Lelystad, the Netherlands.

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Other sources of information

There are a number of websites available on your condition and its treatment, which may provide you with further useful information. Contact the Pancreatic Society of Great Britain and Ireland for assistance.