

Package leaflet: Information for the patient

Pancrex V Powder pancreatin

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

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

The active ingredient in Pancrex V Powder is **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 Powder may also be used when the stomach has been removed, as an aid to digestion.

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

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

Do not take Pancrex V Powder

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

There are no known diseases that may prevent you from taking Pancrex V Powder.

Warnings and precautions

Talk to your doctor or pharmacist before taking Pancrex V Powder.

A rare bowel condition called “fibrosing colonopathy”, where your gut is narrowed, has been reported in patients with cystic fibrosis taking high dose pancreatin products.

If you have cystic fibrosis and take in excess of 10,000 lipase units per kilogram per day and have unusual abdominal symptoms or changes in abdominal symptoms tell your doctor.

Other medicines and Pancrex V Powder

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

Pancrex V Powder is not known to interfere with any other medicines that you may be taking. However, if you are prescribed another medicine, inform the doctor you are taking Pancrex V Powder.

Pregnancy and breast-feeding

If you are pregnant or think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine as dose adjustments may be necessary.

Pancrex V Powder should be used with caution in pregnancy.

Driving and using machines

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

Pancrex V Powder contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Pancrex V Powder

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 Powder 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 and also the clinical outcome. If loose pale stools (faeces) occur you may need to increase the dose. Always check with your pharmacist if you are not sure.

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

- For adults, elderly, and children
0.5 - 2 grams swallowed dry or mixed with a little water or milk before each meal or snack.
- For newborn infants
0.25 - 0.5 grams with each feed.

1 gram of Pancrex V Powder corresponds approximately to the volume of a 1.25 ml spoonful.

2 grams of Pancrex V Powder correspond approximately to the volume of a 2.5 ml spoonful.

A 5 ml measuring spoon is included inside the pack. The spoon can be used to measure doses of 1.25 ml and 2.5 ml.

Ensure you fill the spoon to the correct graduation line.

Wash the spoon in warm water immediately after use and allow to dry.

If the powder is mixed with liquids or feeds, use within one hour.

Pancrex V Powder is taken by mouth.

Pancrex V Powder may be given via a tube direct into the stomach.

If you take more Pancrex V Powder than you should

There are no special precautions to take, although the use of a barrier cream may help prevent possible irritation of the anus.

If you forget to take Pancrex V Powder

Simply skip that dose and take the next dose before your next meal or snack.

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.

It is possible that some people may be allergic (hypersensitive) to Pancrex V Powder.

Allergic/asthmatic reactions have occasionally occurred on handling the powder.

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 Powder, don't take any more. **Tell a doctor straight away and take the packaging and this leaflet with you.**

Very common side effects (affect more than 1 in 10 patients):

- stomach pains

Common side effects (affect 1-10 patients out of 100):

- diarrhoea
- constipation
- feeling or being sick
- bloating

Uncommon side effects (affect 1-10 patients out of 1000):

- skin reactions, such as a rash.

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

- itching with or without a rash
- allergic reactions (which may be severe)
- severe or long-lasting abdominal pain (fibrosing colonopathy).

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.

Some irritation of the skin of the mouth may occur if the powder is kept in the mouth. Irritation of the anus may also occur, which may be prevented by use of the barrier cream.

If you notice any different or unusual pain or discomfort in the abdomen (stomach area), if any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 Powder

Do not store above 25°C.

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

Do not take 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 to protect the environment.

6. Contents of the pack and other information

What Pancrex V Powder contains

- The active substance is Pancreatin BP. BP is a British standard measure of potency (expected biological effect) of a pharmaceutical product.

Each gram of powder contains at least:

- 1400 BP units of free protease, an enzyme that digests protein
- 25000 BP units of lipase, an enzyme that digests fat
- 30000 BP units of amylase, an enzyme that digests starch and sugars

The other ingredient is lactose. See end of section 2 for further information on lactose.

What Pancrex V Powder looks like and contents of the pack

Pancrex V Powder is a white or buff-coloured powder.

Each plastic container holds 100 g, 250 g or 300 g of powder and a 5 ml measuring spoon (PP resin) graduated as 1.25 ml, 2.5 ml and 5 ml.

Not all pack sizes may be marketed.

Internet sites for patients with your condition

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.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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

Manufacturer

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