

**300g
PANCREX V
POWDER**

**Pancreatin
Pancreatin BP Oral Powder**

PABYRN

EAN CODE

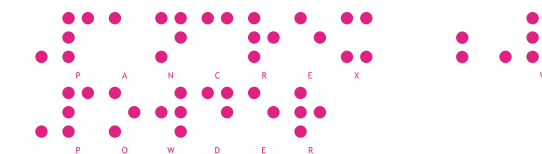
**KEEP ALL MEDICINES OUT OF
CHILDREN'S REACH**

CONTAINS LACTOSE. SEE LEAFLET FOR FURTHER INFORMATION

PL 41094/0004 PanVPow-LPL-UK-1
Essential Pharmaceuticals Ltd
Egham, Surrey, TW20 8RB, UK. **P**

Batch no.:
Manuf. date:
Expiry date:

PANCREATIN BP POWDER
Each gram contains not less than the following activity:
Free protease 1400 B.P. Units
Lipase 25000 B.P. Units
Amylase 30000 B.P. Units
Dose: Dosage should be adjusted according to the needs of the individual patient and the amount and type of food consumed. The following dosage ranges provide a suitable basis for adjustment.
Adults, the elderly and children: 0.5 - 2 grams swallowed dry or mixed with a little water or milk with each snack or meal.
Newborn infants: 0.25 - 0.5 grams with each feed.
If mixed with liquids use within one hour.
Do not store above 25°C.



Pancrex V Powder

4. POSSIBLE SIDE EFFECTS

Like all medicines, Pancrex V Powder 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.**

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, 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. 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 out of the reach and sight of children.

The expiry date for this medicine is on the packaging. Do not take Pancrex V Powder after this date. The expiry date refers to

the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER 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 in Pancrex V Powder 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 300g of powder.

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

The Marketing Authorisation for Pancrex V Powder is held by Essential Pharmaceuticals Ltd, 7 Egham Business Village, Crabtree Road, Egham, Surrey, TW20 8RB, UK.

The powder is manufactured by Dales Pharmaceuticals Ltd, Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, UK.

This leaflet was last revised in 12/2016.

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Tear here, but do not remove

Patient Information Leaflet

Pancrex V Powder

Pancreatin

Read all of this leaflet carefully before you start taking this medicine. 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 is available without prescription. However, you still need to take Pancrex carefully to get the best results from it. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Pancrex V Powder is and what it is used for
2. 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. Further 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. BEFORE YOU TAKE PANCREX V POWDER

Do not take Pancrex V Powder if you

- are **allergic** (hypersensitive) to **pancreatin**

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

Taking 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, thinking of becoming pregnant or breast-feeding, discuss this with your doctor before taking your medicine as dose adjustments may be necessary. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

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

Important information about some of the ingredients of Pancrex V Powder

- **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

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. 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, 0.5g-2g swallowed dry or mixed with a little water or milk before each meal or snack.
- For newborn infants, 0.25g-0.5g with each feed.

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 product, ask your pharmacist.