

**PANCREX V
FORTE
TABLETS**
Pancreatin
Pancreatin Tablets BP
300 TABLETS

PABYRN

EAN CODE

Batch no.:
Manuf. date:
Expiry date:

PANCREATIN TABLETS B.P.
Each enteric coated tablet contains not less than the following activity:
Free protease 330 B.P. Units
Lipase 5600 B.P. Units
Amylase 5000 B.P. Units
DOSE: Adults, the elderly and children: 6-10 tablets taken whole before meals.
Store at a temperature not exceeding 15°C.

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

CONTAINS LACTOSE. SEE LEAFLET FOR FURTHER INFORMATION

PL 41094/0008 EP00205 P

Essential Pharmaceuticals Ltd
Egham, Surrey, TW20 8RB, UK.

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 tablets are chewed or the contents kept in the mouth. Irritation of the anus may also occur, which may be prevented by use of the barrier cream.

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 FORTE TABLETS

Store at, or below, 15°C. This is best achieved by storing the container in the fridge.

Keep out of the reach and sight of children.

The expiry date for this medicine is on the packaging. Do not take Pancrex V Forte Tablets 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 Forte Tablets contain

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

Each tablet contains at least:

- 330 BP units of free protease, an enzyme that digests protein
- 5600 BP units of lipase, an enzyme that digests fat
- 5000 BP units of amylase, an enzyme that digests starch and sugars

Each tablet also contains: lactose, povidone, stearic acid, Opaseal P17-28901 (containing IMS, titanium dioxide (E171), polyvinyl acetate phthalate, and stearic acid (E570)), talc, sucrose, acacia, calcium carbonate, titanium dioxide, Opalus AS 7000B (containing sucrose, sodium benzoate (E211), titanium dioxide (E171), and indigo carmine aluminium lake (E132)), syrup, Opagloss 6000P (containing

ethanol, shellac (E904), white beeswax (E901), yellow carnuba wax (E903)).

Pancrex V Forte Tablets contain approximately 0.13g of lactose. When taken as recommended (see section 3 'How to take Pancrex V Forte Tablets') each dose supplies up to 1.3g of lactose.

What Pancrex V Forte Tablets look like and contents of the pack

Pancrex V Forte Tablets are white, enteric- and sugar-coated tablets. Each plastic container holds 300 tablets.

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 Forte Tablets is held by Essential Pharmaceuticals Ltd, 7 Egham Business Village, Crabtree Road, Egham, Surrey, TW20 8RB, UK.

The tablets are manufactured by Penn Pharmaceuticals Ltd., Tredegar, Gwent, NP2 3AA, South Wales, UK

This leaflet was last approved in August 2015

EP00205

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Tear here, but do not remove

Patient Information Leaflet

Pancrex V Forte Tablets 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 Forte Tablets are and what they are used for
2. Before you take Pancrex V Forte Tablets
3. How to take Pancrex V Forte Tablets
4. Possible side effects
5. How to store Pancrex V Forte Tablets
6. Further information

1. WHAT PANCREX V FORTE TABLETS ARE AND WHAT THEY ARE USED FOR

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

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

2. BEFORE YOU TAKE PANCREX V FORTE TABLETS

Do not take Pancrex V Forte Tablets if you

- are **allergic** (hypersensitive) to **pancreatin** or **any of the other ingredients** of Pancrex V Forte Tablets (see list in section 6 'Further Information')
- **cannot easily digest or absorb milk sugars** (lactose, galactose, glucose). Contact your doctor or pharmacist before taking Pancrex V Forte Tablets if you think this might be the case.

Taking other medicines

Pancrex V Forte Tablets are 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 Forte Tablets.

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 Forte Tablets do not interfere with your ability to drive or operate machinery.

Important information about some of the ingredients of Pancrex V Forte Tablets

This product contains **lactose** and **sucrose**. If you are **lactose or sucrose intolerant**, contact your doctor or pharmacist before taking this product.

3. HOW TO TAKE PANCREX V FORTE TABLETS

Dosage

Your doctor or pharmacist will advise you on the amount of Pancrex V Forte Tablets 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.

You may notice variations in response to Pancrex V Forte Tablets, which can be due to the special coating of the tablets.

For adults, elderly, and children, 6-10 tablets before each meal or snack should provide a good starting point for adjustment of the dose. Each tablet should be swallowed whole and not chewed.

If you take more Pancrex V Forte Tablets 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 Forte Tablets

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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Pancrex V Forte Tablets can cause side effects, although not everybody gets them.

It is possible that some people may be allergic (hypersensitive) to Pancrex V Forte Tablets. **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 Forte Tablets, don't take any more. **Tell a doctor straight away and take the packaging and this leaflet with you.**