

Label for the label-leaflet

300g Pancrex Granules Pancreatin Pancreatin BP Granules PABYRN logo EAN code

PANCREATIN GRANULES B.P.

Each gram contains not less than the following activity:

Free protease 300 B.P. Units

Lipase 5000 B.P. Units

Amylase 4000 B.P. Units

DOSE: As directed by the physician, swallowed dry or taken mixed in a little soft food or liquid just before or with meals. Average dose for adults, the elderly and children: 5-10 grams four times daily.

When mixed with liquids use within one hour.

Store at a temperature not exceeding 15°C.

KEEP ALL MEDICINES OUT OF CHILDREN'S REACH

INCLUDES LACTOSE

see leaflet for further information

PL 41094/0003

UK Only

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

Braille reading: Pancrex Granules

Batch no.:

Manuf. date: Expiry

date:

Patient Information Leaflet

Pancrex Granules

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 Granules carefully to get the best results from them. 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 Granules are and what they are used for
2. Before you take Pancrex Granules
3. How to take Pancrex Granules
4. Possible side effects
5. How to store Pancrex Granules
6. Further information

1. WHAT PANCREX GRANULES ARE AND WHAT THEY ARE USED FOR

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

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

2. BEFORE YOU TAKE PANCREX GRANULES

Do not take Pancrex Granules if you – are allergic (hypersensitive) to pancreatin or any of the other ingredients of

Pancrex Granules (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 Granules if you think this might be the case.

Taking other medicines

Pancrex Granules 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 Granules.

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

Important information about some of the ingredients of Pancrex Granules

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

3. HOW TO TAKE PANCREX GRANULES

Dosage

Your doctor or pharmacist will advise you on the amount of Pancrex Granules 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.

For adults, elderly, and children, 5g-10g of granules swallowed dry or mixed with a little water or milk just before meals should provide a good starting point for adjustment of the dose.

If the granules are mixed with liquids or food, use within one hour.

If you take more Pancrex Granules 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 Granules

Simply skip that dose and take the next dose with your next meal.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Pancrex Granules can cause side effects, although not everybody gets them.

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

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 Granules, 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 capsules are chewed or kept in the mouth. Irritation of the anus may also occur, which may be prevented by use of a 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 GRANULES

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

Keep out of the reach and sight of children.

Do not use Pancrex Granules after the expiry date which is stated on the pack after **Expiry 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 Granules contain

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

Each gram of granules contains at least:

- 300 BP units of free protease, an enzyme that digests protein
- 5000 BP units of lipase, an enzyme that digests fat
- 4000 BP units of amylase, an enzyme that digests starch and sugars

The other ingredients are lactose, acacia (E414), Opaseal P17-0200 containing IMS, polyvinyl acetate phthalate and stearic acid (E570).

Pancrex Granules contain approximately 70g of lactose per 100g. When taken as recommended (see section 3 “How to take Pancrex Granules”) each dose supplies up to 7g of lactose.

What Pancrex Granules look like and contents of the pack

Pancrex Granules are light to dark buff-coloured coated granules. Each plastic container holds 300g of granules.

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 Granules is held by Essential Pharmaceuticals Ltd, 8a Crabtree Road, Egham, Surrey, TW20 8RN, UK.

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

This leaflet was last approved in 06/2024.