

Pangrol® 10 000

10,000 Ph. Eur. Units lipase

Hard gastro-resistant capsules

Active substance: pancreas powder from pigs

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 Pangrol 10 000 is and what it is used for
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1. What Pangrol 10 000 is and what it is used for

What Pangrol 10 000 is

Pangrol 10 000 is a medicine that contains digestion-promoting substances (enzymes) from the pancreas of pigs (pancreas powder, also called pancreatin).

What Pangrol 10 000 is used for

It is used to treat digestive disturbances caused by a decreased or absent function of the pancreas.

2. What you need to know before you take Pangrol 10 000

Do not take Pangrol 10 000

- If you are allergic to pancreas powder, pork or any of the other ingredients of this medicine (listed in Section 6)
- If you are suffering from an acute inflammation of the pancreas or have an acute attack of a chronic inflammation of the pancreas during the fully blown phase of the disease. However, administration of Pangrol 10 000 is occasionally appropriate in the resolving phase during dietary build-up (bland diet) when digestive disturbances persist.

Warnings and precautions

Talk to your doctor or pharmacist before taking Pangrol 10 000

- 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 Ph. Eur. Units lipase per kilogram body weight per day, **tell your doctor**. As a precaution, unusual abdominal symptoms or changes in abdominal symptoms should be investigated.
- If an allergic reaction occurs, stop your treatment and talk to your doctor. An allergic reaction could include itching, hives or rash. In some cases, a serious allergic reaction may occur, for example with severe skin reactions, swelling, a feeling of warmth, dizziness and fainting, trouble breathing, racing heart (see section 4. "Possible side effects"); these are symptoms of a severe, potentially life-threatening condition called "anaphylactic shock". If this occurs, call for urgent medical attention **straight away**.
- This medicine contains active enzymes that, when released in the oral cavity (e.g. through chewing), may cause mucous membrane damage (e.g. wounds in the mucous membrane of the mouth). Therefore, take care to swallow Pangrol 10 000 **whole**.

Other medicines and Pangrol 10 000

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

The absorption of **folic acid** (uptake of folic acid into the blood) may be decreased by taking pancreas powder-containing finished medicines, meaning that additional folic acid administration may be required.

The effect of the **blood sugar-lowering active substances acarbose and miglitol** may be lowered by taking Pangrol 10 000 at the same time.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

There are no adequate data on the use of Pangrol 10 000 in pregnant women. There are only insufficient data from animal studies with regard to pregnancy, development of the unborn child, delivery and development of the child after birth. The possible risk for humans is not known. If you are pregnant or you are breast-feeding, you should not take Pangrol 10 000 unless your doctor feels taking it to be absolutely necessary.

Driving and using machines

Pangrol 10,000 has no or negligible influence on driving and using machines.

Pangrol 10 000 contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium free".

3. How to take Pangrol 10 000

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dosage

The recommended dose is:

2 - 4 Pangrol 10 000 capsules per meal (equivalent to 20,000 to 40,000 Ph. Eur. Units lipase per meal).

The dosage is in line with the severity of the digestive disturbance; the required dose may therefore also be above that.

An increase in the dose should only be performed under the supervision of a doctor and be aimed at improving the symptoms (e.g. fatty stools, abdominal pain). A daily enzyme dose of 15,000 to 20,000 Units lipase per kilogram of body weight should not be exceeded.

Particularly in patients with cystic fibrosis, the enzyme dose should not be higher than necessary for appropriate fat intake (see below "If you take more Pangrol 10 000 than you should" and section 2. "Warnings and precautions").

The doctor should decide about the dosage in children.

Method of use

Swallow the capsule **whole** with plenty of liquid, preferably in the middle of a meal.

If you have difficulty swallowing the capsule whole, you can also open it carefully over a suitable container by pulling it apart and swallow only the contents with some liquid immediately and without chewing.

You should drink plenty of liquid (water or juice) afterwards.

Please take care not to **crush or chew** the capsules or their contents (minitablets), as Pangrol 10 000 loses effectiveness, and the enzymes contained may damage the mucous membrane when released in the oral cavity.

Length of use

The length of use is not subject to any restriction. It is in line with the course of the disease and is determined by the doctor. You must talk to a doctor if you do not feel better or if you feel worse.

Please speak to your doctor if you have the impression that the effect of Pangrol 10 000 is too strong or too weak.

If you take more Pangrol 10 000 than you should

Drink a lot of water afterwards and speak to your doctor or pharmacist.

Repeated high doses of pancreas powder can also cause scarring or thickening of the bowel wall that can lead to blockage of the intestines, a condition called fibrosing colonopathy (see above "How to take Pangrol 10 000" and section 2. "Warnings and precautions").

Extremely high doses of pancreas powder, especially in cystic fibrosis patients, may lead to an increase in uric acid in the blood (hyperuricaemia) and urine (hyperuricosuria).

If you forget to take Pangrol 10 000

Do not take a double dose to make up for a forgotten dose but please continue with the treatment as recommended.

If you stop taking Pangrol 10 000

If you end treatment early or interrupt it, you must expect that your complaints may return. Consult your doctor.

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.

The following side effects may happen with this medicine.

The most important serious side effects seen with pancreatic enzyme replacement medicines are "anaphylactic shock" and fibrosing colonopathy. These two side effects have occurred in a very small number of people, but their exact frequency is unknown (cannot be estimated from the available data).

Anaphylactic shock is a severe, potentially life-threatening allergic reaction that can develop rapidly. If you notice any of the following seek urgent medical attention **straight away**:

- Itching, hives (urticaria) or rash
- Swollen face, eyes, lips, hands or feet
- Feeling lightheaded or faint
- Trouble breathing or swallowing
- Palpitations
- Dizziness, collapse or unconsciousness

Repeated high doses of pancreatic enzyme replacement medicines can also cause scarring or thickening of the bowel wall that can lead to blockage of the intestines, a condition called fibrosing colonopathy (see section 2. "Warnings and precautions"). If you have severe stomach pain, trouble passing stools (constipation), nausea or vomiting, tell your doctor **straight away**.

Very common side effects: may affect more than 1 in 10 people

- Pain in your stomach (abdomen)

Common side effects: may affect up to 1 in 10 people

- Feeling sick (nausea)
- Being sick (vomiting)
- Constipation
- Bloating (abdominal distension)
- Diarrhoea

These may be due to the condition you are taking Pangrol 10 000 for.

Uncommon side effects: may affect up to 1 in 100 people

- Rash

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 Federal Institute for Drugs and Medical Devices, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, website: www.bfarm.de. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pangrol 10 000

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

Do not store above 25 °C.

In the case of packaging in a container, the following also applies:

Keep the container tightly closed.

Shelf life after first opening: 6 months

Do not use this medicine after the expiry date which is stated on the outer carton (folding box) and on the label or the blister 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. You will find further information under www.bfarm.de/azneimittelentsorgung.

6. Contents of the pack and other information

What Pangrol 10 000 contains

The active substance is pancreas powder from pigs.

Each hard gastro-resistant capsule (hard capsule with gastro-resistant minitabets) contains 75.6 - 137.4 mg of pancreas powder, manufactured from the pancreatic tissue of pigs, equivalent to:

- Lipase activity 10,000 Ph. Eur. Units
- Amylase activity not less than 9,000 Ph. Eur. Units
- Protease activity not less than 500 Ph. Eur. Units

The other ingredients are:

Hydrogenated castor oil; colloidal anhydrous silica; magnesium stearate (Ph. Eur.) [vegetable]; croscarmellose sodium; microcrystalline cellulose; methacrylic acid - ethyl acrylate copolymer (1:1 dispersion) 30 per cent (Ph. Eur.); talc; triethyl citrate; simeticone emulsion 30 %; iron(III) oxide (E 172); iron(III) hydroxide oxide × H₂O (E 172); indigo carmine (E 132); quinoline yellow (E 104); titanium dioxide; gelatin.

What Pangrol 10 000 looks like and contents of the pack

Pangrol 10 000 hard capsules consist of a yellow-green cap and a light orange body and contain light brown, shiny, homogeneous minitablets (gastro-resistant coated). The capsules are packaged in blisters or filled into polypropylene containers sealed with a polyethylene closure with desiccant. The blisters or containers are packaged in an outer carton (folding box) together with the package leaflet.

Pangrol 10 000 comes in packs of 20, 50 (N1), 100 (N2) and 200 (2 × 100) hard gastro-resistant capsules (N3).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

BERLIN-CHEMIE AG
Glienicker Weg 125, 12489 Berlin, Germany

This leaflet was last revised in .

We wish you a rapid recovery!

At this point, a further piece of information for patients of the Islamic faith: You too can take Pangrol 10 000.

Please allow us to point out the following. Verse 173 of the 2nd Surah of the Koran says:

Turkish:

Allah size ölü (boğazlanmamış hayvanın) etini, akan kanı, domuz etini ve Allah'tan başkası (putlar) için kesilmiş hayvanı haram etmiştir. Fakat helâk olacak derecede zorda kalan, istemeyerek ve zaruret miktarını aşmayarak bunlardan yerse, günah işlemiş sayılmaz. Şüphesiz ki, Allah çok bağışlayıcı ve çok rahmet sahibidir.

English:

He hath only forbidden you dead meat, and blood, and the flesh of swine, and that on which any other name hath been invoked besides that of Allah. But if one is forced by necessity, without wilful disobedience, nor transgressing due limits, – then is he guiltless. For Allah is Oft-forgiving Most Merciful.