

Package leaflet: Information for the user

## ***Pangrol<sup>®</sup> 10 000***

10,000 Ph. Eur. units of lipase

Enteric-coated hard capsules

Active ingredient: Pancreas powder from pork

**Read the entire patient information leaflet carefully before you start taking this medication, as it contains important information.**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Please retain this patient information leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you notice any side effects, please notify 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
2. What you need to know before you take Pangrol 10 000
3. How to take Pangrol 10 000
4. Possible side effects
5. How to store Pangrol 10 000
6. Contents of the pack and other information

## **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 digestive substances (enzymes) from porcine pancreas (pancreas powder, also called 'pancreatin').

### **What Pangrol 10 000 is used for**

It is used to treat digestive disorders caused by reduced or absent pancreatic function.

## 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 medication listed in section 6.
- if you suffer from acute inflammation of the pancreas or have an acute episode of chronic inflammation of the pancreas during the full-blown phase of the disease. However, in the phase when symptoms have subsided during dietary build-up (light diet), the administration of Pangrol 10 000 is occasionally useful if digestive disorders persist.

### Warnings and precautions

Please talk to your doctor or pharmacist before taking Pangrol 10 000.

- In patients with cystic fibrosis, a rare intestinal disease called "fibrosing colonopathy", in which your intestines are narrowed, has been reported when taking high-dose pancreatic powder products. **Tell your doctor** if you have cystic fibrosis and are taking more than 10,000 Ph. Eur. units of lipase per kilogram of body weight per day. As a precaution, any unusual abdominal discomfort or changes in abdominal symptoms should be examined.
- If an allergic reaction occurs, stop your treatment and talk to your doctor. An allergic reaction could include itching, hives, or a rash. In some cases, a serious allergic reaction may occur, e.g. with severe skin reactions, swelling, warmth, dizziness and fainting, difficulty breathing, tachycardia. (See section 4. "Possible side effects"). These are symptoms of a severe, potentially life-threatening condition called "anaphylactic shock". If this is the case, call for medical help **immediately**.
- This medicine contains active enzymes which, when released into the oral cavity (e.g. by chewing), can cause mucosal damage (e.g. sores in the oral mucosa). Therefore, make sure that you take Pangrol 10 000 **without chewing it**.

### Taking Pangrol 10 000 with other medications

Please tell your doctor or pharmacist if you are using or have recently used any other medicines or intend to use other medicines.

The absorption of **folic acid** (absorption of folic acid into the blood) can be reduced by taking ready-to-use medicines containing pancreatic powder, so that an additional folic acid intake may be necessary.

The effect of the **blood sugar-lowering active ingredients acarbose and miglitol** can be reduced by taking Pangrol 10 000 at the same time.

## **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, ask your doctor or pharmacist for advice before using all medicines.

There is not enough experience of the use of Pangrol 10 000 in pregnant women. There is insufficient data from animal studies on pregnancy, development of the unborn child, delivery and development of the child after birth. The possible risk to humans is not known. If you are pregnant or breast-feeding, you should not take Pangrol 10 000 unless the doctor treating you deems it absolutely necessary.

## **Driving and operating machinery**

Pangrol 10 000 has no or negligible influence on the ability to drive and operate machinery.

## **Pangrol 10 000 contains sodium**

This medicine contains less than 1 mmol (23 mg) of sodium per tablet, which means it is almost sodium-free.

## **3. How to take Pangrol 10 000**

Always take this medication exactly as instructed by your doctor. Check with your doctor or pharmacist if you are not sure.

### **Posology**

The recommended dose is:

**2–4 capsules of Pangrol 10 000 per meal** (equivalent to 20,000 to 40,000 Ph. Eur. units of lipase per meal).

The dosage depends on the severity of the indigestion, so the required dose may be higher.

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

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

The doctor should decide on the dosage in children.

### **Method of administration**

Take 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 carefully open it over a suitable container by pulling it apart and swallowing only the contents with a little liquid immediately and without chewing.

You should drink plenty of fluids (water or juice).

Please ensure that you do not **crush or chew** the capsules or their contents (mini-tablets), otherwise Pangrol 10 000 will lose its effect and the enzymes it contains may damage the mucous membranes if released into the oral cavity.

### **Duration of use**

There is no limit to the duration of use. It depends on 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.

Talk to your doctor or pharmacist 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 plenty of water and talk to your doctor or pharmacist.

Repeated high doses of pancreas powder can scar or thicken the intestinal wall, which can lead to intestinal obstruction, a condition known as "fibrosing colonopathy". (See "How to take Pangrol 10 000" and section 2, "Warnings and precautions".)

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

### **If you forget to take Pangrol 10 000**

Do not take double the amount if you forget to take the previous dose, but please continue with the treatment as recommended.

### **If you stop taking Pangrol 10 000**

If you stop or interrupt treatment prematurely, you can expect your symptoms to return. Consult your doctor.

If you have any further questions about the use of the medicine, consult 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 occur with this medicine.

The main serious side effects that occur with pancreatic enzymes are anaphylactic shock and fibrosing colonopathy. These two

side effects have occurred in a very small number of people, but their exact frequency is not known (cannot be estimated based on the available data).

Anaphylactic shock is a severe, potentially life-threatening allergic reaction that can develop quickly. Stop taking Pangrol 10 000 and seek medical attention **immediately** if you experience any of the following:

- Itching, hives (urticaria) or rash
- Swollen face, eyes, lips, hands or feet
- Feeling lightheaded or weak
- Difficulty breathing or swallowing
- Palpitations
- Dizziness, collapse or loss of consciousness.

Repeated high doses of pancreatic enzyme replacement medications can also scar or thicken the intestinal wall, which can lead to intestinal obstruction, a condition known as "fibrosing colonopathy". (See section 2, "Warnings and precautions".) Tell your doctor **immediately** if you have severe abdominal pain, difficulty defecating (constipation), nausea or vomiting.

#### **Very common side effects (may affect more than 1 in 10 people):**

- Abdominal pain.

#### **Common side effects (may affect up to 1 in 10 people):**

- Nausea
- Vomiting
- Constipation
- Flatulence
- Diarrhoea

This may be due to the conditions for which you are taking Pangrol 10 000.

#### **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 to the Bundesinstitut für Arzneimittel und Medizinprodukte, (Federal Institute for Drugs and Medical Devices), Department of Pharmacovigilance, Kurt-Georg-Kiesinger Allee 3, D-53175 Bonn, Germany, website: [www.bfarm.de](http://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 containers, the following also applies: Keep the container tightly sealed.

Shelf life after opening: 6 months

Do not use the medicine after the expiry date which is stated on the outer carton (folding box) and on the label or blister pack (push-through pack) after "EXP". The expiry date refers to the last day of that month.

Never dispose of any medication via wastewater (e.g. not down the toilet or sink). Ask your pharmacist how to dispose of medication you no longer use. By doing so, you are helping to protect the environment. For more information, see [www.bfarm.de/arzneimittelentsorgung](http://www.bfarm.de/arzneimittelentsorgung).

## 6. Contents of the pack and other information

### What Pangrol 10 000 contains

The active ingredient is pancreatic powder from pigs.

One enteric-coated hard capsule (hard capsule with enteric-coated mini-tablets) contains 75.6 - 137.4 mg pancreatic powder, made from pancreatic tissue from pigs, corresponding to:

- Lipase activity 10 000 Ph. Eur. units
- Amylase activity at least 9,000 Ph. Eur. units
- Protease activity at least 500 Ph. Eur. units.

The other ingredients are:

Hydrogenated castor oil, highly dispersed silicon dioxide, magnesium stearate (Ph. Eur.) [vegetable], croscarmellose sodium, microcrystalline cellulose, methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30% (Ph. Eur.), talc, triethyl citrate, simeticone emulsion 30%, iron(III) oxide (E 172), iron(III) hydroxide oxide x H<sub>2</sub>O (E 172), indigo carmine (E 132), Quinoline Yellow (E 104), titanium dioxide, gelatine.

### 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 mini-tablets (enteric coating). The capsules are packaged in push-through packs or filled in polypropylene containers, which are closed with a polyethylene closure with desiccant. The push-through packs or containers are packed in an outer carton (folding box) together with the leaflet.

Pangrol 10 000 is available in packs of 20, 50 (N1), 100 (N2) and 200 (2 x 100) enteric-coated hard capsules (N3).

Not all pack sizes may be available on the market.

### Pharmaceutical company and manufacturer

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

**This patient information leaflet was last revised in June 2023.**

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**We wish you a speedy recovery!**

At this point, some information for patients of Islamic faith: You can also take Pangrol 10 000. Please allow us to point this out. The 173rd verse of the 2nd Sura of the Qur'an states:

**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 has only forbidden you to eat carrion, blood, swine, and what is slaughtered in the name of any other than Allah. But if someone is compelled by necessity - neither driven by desire nor exceeding immediate need - they will not be sinful. Surely Allah is All-Forgiving, Most Merciful.