

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### PANGROL 10 000

Gastro – resistant capsule, hard

#### PANCREATIN

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

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#### What is in this leaflet?

1. What PANGROL 10 000 is and what it is used for
2. 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. Further information

#### 1. WHAT PANGROL 10 000 IS AND WHAT IS IT USED FOR

PANGROL 10 000 contains digestive enzymes of the pancreas (pancreas enzymes).

PANGROL 10 000 serves for the replacement of digestive enzymes in digestive disturbances (maldigestion) as a result of inadequate or absent function of the pancreas (exocrine pancreatic insufficiency) or reduced influence of digestive enzymes in the intestines.

This may occur due to:

- Chronic inflammation of the pancreas (chronic pancreatitis)
- characteristic functional disorders of the pancreas (cystic fibrosis)
- problems caused by a tumor or gallstones
- malfunction of the liver and gallbladder,
- operation of the pancreas,
- accelerated flow through the intestines after gastric or intestine surgery, anxiety or inflammatory bowel disease
- consumption of certain foods, which leads to difficulties with absorption of nutrients, and dysfunction of the digestive organs associated with loss of appetite, belching, retching and diarrhea
- Celiac disease

- inflammatory bowel disease (especially Crohn's disease)
- diabetes (Diabetes mellitus),
- acquired Immune Deficiency Syndrome (AIDS),
- (Shwachmanovog syndrome)
- Sjögren's syndrome

## 2. BEFORE YOU TAKE PANGROL 10 000

### **Do not take PANGROL 10 000**

- If you are allergic (hypersensitive) to active substance, pork or any of the other ingredients of PANGROL 10 000.
- In acute inflammation or acute episodes of chronic inflammation of the pancreas during the fully-blown phase of the disease. However, occasional administration is appropriate in the subsiding phase of the disease during dietary build-up if there is evidence of impairment to the pancreatic function remaining or persisting.

### **Take special care with PANGROL 10 000**

- In intestinal obstruction-like symptoms. Intestinal obstruction is a known complication in patients with cystic fibrosis. The possibility of intestinal narrowing should therefore also be considered in the presence of intestinal obstruction-like symptoms, and you need to immediately stop taking PANGROL 10 000 and contact your doctor.
- As PANGROL 10 000 contains active enzymes that, on release in the oral cavity, for example through chewing, may lead to mucous-membrane damage (ulcerations). Care is therefore to be taken to swallow PANGROL 10 000 whole.

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. The absorption of folic acid (uptake of folic acid into the blood) may be lessened 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 (oral antidiabetics) acarbose and miglitol may be lowered by taking PANGROL 10 000 at the same time.

### **Taking PANGROL 10 000 with food and drink**

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

### **Pregnancy and breast-feeding**

You can take PANGROL 10 000 in pregnancy and breast-feeding after consulting your doctor.

### **Driving and using machines**

No special precautions are required.

## 3. HOW TO TAKE PANGROL 10 000

Always take PANGROL 10 000 exactly according to the instructions in this package leaflet. You should check with your doctor or pharmacist if you are not sure.

### **Dosage**

The most common dose is recommended for 20,000 to 40,000 lipase units per meal. Unless otherwise prescribed, 2 - 4 capsules are generally taken during a meal. The required dose may also be above that. An

increase in the dose should take place only under the supervision of a doctor and be aimed at an improvement in the symptoms (e.g. fatty stools, stomachache). A daily enzyme dose of 15,000 - 20,000 units of lipase per kg body weight should not be exceeded. Treatment with PANGROL 10 000 aims to achieve or maintain a normal body weight and normalizes the frequency or consistency of stool.

The doctor should decide as to the dosage in children.

#### Method of administration

PANGROL 10 000 should be swallowed whole with plenty of liquid (water or juice) in the middle of the meal.

Patients who have troubles to swallow the capsule can open it, empty the contents into another container (eg, glass) and immediately swallow it with a small amount of liquid.



#### Duration of treatment

The length of use of PANGROL 10 000 is in line with the course of the disease and is determined by your doctor. Consult your doctor if your symptoms do not improve or if they get worse after 7-14 days of starting treatment. Please speak 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***

The quantity of PANGROL 10 000 taken may also be substantially above the recommended dose. Harmful effects are not expected.

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

Do not take double dose to make up for a forgotten capsule.

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

If you end treatment with PANGROL 10 000 early, or if you interrupt treatment, then it is expected that the desired therapeutic effect will not set in, or that your condition of "bad digestion" will get worse again.

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

#### ***4. POSSIBLE SIDE EFFECTS***

Like all medicines, PANGROL 10 000 can cause side effects, although not everybody gets them.

#### **Important side effects or signs that you should pay attention to, and measures if you are affected:**

If you are affected by one of the side effects stated below, do not take PANGROL 10 000 any longer and go to your doctor at once if possible.

#### **Very rare side effects (may affect less than 1 user in 10,000)**

**Stomach and digestive system:** Narrowing of the lower sections of the intestines have been described in patients with cystic fibrosis following administration of high doses of pancreas powder (the active substance of PANGROL 10 000).

Hypersensitivity reactions of the digestive tract (such as diarrhea, stomach discomfort and nausea) have been described after pancreas powder was taken.

**Immune system:** Hypersensitivity reactions of the immediate type (like skin rash, sneezing, flow of tears and breathlessness due to spasms of the bronchial tubes) have been described after pancreas powder was taken.

**Frequency of side effects not known (cannot be estimated from the available data):**

**Kidneys and urinary system:** Increased uric acid excretion with the urine may occur in patients with cystic fibrosis, especially when high doses of pancreas powder are taken. If you are a cystic fibrosis patient, your doctor will therefore check uric acid excretion with the urine in order to avoid the formation of uric acid stones.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**Reporting of suspected 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.

**5. HOW TO STORE PANGROL 10 000**

Keep out of the reach and sight of children.

Do not use PANGROL 10 000 after the expiry date which is stated on the outer carton and container film after EXP. The expiry date refers to the last day of that month.

Storage conditions:

Do not store above 25°C.

The medicine may be used 6 months after opening.

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 PANGROL 10 000 contains**

The active substance is:

1 gastro-resistant capsule contains:

pancreatin 153,5 mg

Lipase activity 10,000 Ph. Eur. Units/capsule

Amylase activity not less than 9000 Ph. Eur. Units/capsule

Protease activity not less than 500 Ph. Eur. Units/capsule

The other ingredients are:

Core: croscarmellose sodium, microcrystalline cellulose, hydrogenated castor oil, colloidal anhydrous silica, magnesium stearate (Ph. Eur.) [Veg.].

Shell: methacrylic acid - ethyl acrylate copolymer (1: 1) dispersion 30%, talc, triethyl citrate, simethicone emulsion contains 30%: Simethicone, polyethylene glycol sorbitan tristearate, methyl cellulose, hydroxy-substituted dimethylsiloxane, macrogol stearate, mono- and di-glycerides, macrogol, xanthan gum,

triglycerides, benzoic acid, glycerol, sodium chloride, octamethylcyclotetrasiloxane, sorbic acid, sulfuric acid, purified water.

Capsule:

Iron (III) oxide (E172), iron (III) hydroxide oxide x H<sub>2</sub>O (E 172), indigo carmine (E 132), quinoline yellow (E 104), titanium dioxide (E 171), gelatin.

***What PANGROL 10 000 looks like and contents of the pack***

PANGROL 10 000 are yellowish green gelatin capsules with light brown, bright, homogeneous gastro-resistant mini-tablets.

Primary Packaging: Plastic (PP) bottle with a PE cap.

Original package with 20 capsules.

***Regime of dispensing***

The medicine is issued on prescription.

***Manufacturer***

Berlin-Chemie AG, Glienicke Weg 125, D-12489 Berlin, Germany