

Package leaflet: Information for the user

Pangrol 25 000 units gastro-resistant hard capsules porcine pancreas powder

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 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 after 7-14 days.

What is in this leaflet

1. What Pangrol 25 000 units gastro-resistant hard capsules (further Pangrol 25 000) is and what it is used for
2. What you need to know before you take Pangrol 25 000
3. How to take Pangrol 25 000?
4. Possible side effects
5. How to store Pangrol 25 000?
6. Contents of the pack and other information

1. What Pangrol 25 000 is and what it is used for

What is Pangrol 25 000?

Pangrol 25 000 is a medicine that contains digestion-promoting substances (pancreas) from the pancreas of pigs (pancreas powder).

What is Pangrol 25 000 used for?

Pangrol 25 000 serves for the replacement of digestive enzymes in digestive disturbances (maldigestion) as a result of inadequate or absent supply of digestive enzymes by the pancreas or reduced action of digestive enzymes in the intestine. This may be associated for example with:

- Long-standing inflammation of the pancreas (chronic pancreatitis) of any origin (alcohol-induced, traumatic, autoimmune, hereditary, drug-induced, tropical calcifying, idiopathic),
- Cystic fibrosis (an inherited disease of the mucous glands affecting various organs),
- Constriction of the pancreas duct for example by tumors or gall stones,
- Previous pancreas operations,
- Accelerated passage of food through the intestines after stomach and intestinal operations, nervousness or infectious intestinal diseases,
- The consumption of poorly digestible vegetable, fatty and unfamiliar foods leading to impairment to nutrient absorption and indigestion associated with lack of appetite, belching, retching and diarrhoea (dyspepsia)
- Disturbances in the liver/gallbladder system,
- Coeliac disease (an autoimmune disorder of the small intestine),
- Inflammatory bowel disease (especially Crohn's disease),
- Diabetes mellitus,
- Acquired immunodeficiency syndrome (AIDS),
- Shwachman syndrome ,
- Sjögren's syndrome

2. What you need to know before you take Pangrol 25 000

Do not take Pangrol 25 000

- If you are allergic to pancreas powder, to 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 episode of a 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.

Warnings and precautions

Talk to your doctor or pharmacist before using Pangrol 25 000

- if you notice that you have bowel obstruction-like complaints (e.g. abdominal pain, lacking bowel function, nausea, vomiting). Intestinal obstruction is a known complication in patients with cystic fibrosis.
- This medicine contains active enzymes that, on release in the oral cavity, for example through chewing, may lead to mucous-membrane damage (e.g. wounds in the mucous membrane of the mouth). Care is therefore to be taken to swallow Pangrol 25 000 whole.

Other medicines and Pangrol 25 000

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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 25 000 at the same time.

Pregnancy and breast-feeding

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

Pregnancy

There is no sufficient experience with the use of Pangrol 25 000 in pregnant women. Only insufficient data from animal-experienced studies exist regarding pregnancy, development of the unborn child, delivery and development of the child after birth. The possible risk for humans is not known.

Breast-feeding

If you are pregnant or you are breast-feeding, you should not take Pangrol 25 000 unless your doctor feels taking it to be absolutely necessary.

Driving and using machines

Pangrol 25 000 has no or negligible influence on the ability to drive and use machines.

3. How to take Pangrol 25 000?

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

The recommended dose of the preparation is:

1 Pangrol 25 000 capsules per meal (equivalent to 25,000 Ph. Units lipase per meal)

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

An increase in the dose should take place only with checking by 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 of body weight should not be exceeded. Particularly in patients with cystic fibrosis the dose of enzymes should not be higher than needed for an adequate fat resorption.

Use in children and adolescents

The doctor should decide as to the dosage in children.

Method of administration

Pangrol 25 000 should be swallowed whole with plenty of liquid in the middle of the meal.

Patients who do not wish to swallow the whole capsule can open them by pulling them apart over a suitable container, like a glass for example, and swallow whole only the contents with a little liquid.



Take care that tablets are swallowed whole as the effectiveness of Pangrol 25 000 is reduced by chewing and the enzymes contained may after release damage the oral cavity mucosa. Drink a lot of fluid (water or juice) afterwards.

Duration of treatment

The duration of treatment is not restricted. The length of use of Pangrol 25 000 is in line with the course of the disease and is determined by your doctor.

Please talk to your doctor if you do not feel better or if you feel worse.

Please speak to your doctor or pharmacist if you have the impression that the effect of Pangrol 25 000 is too strong or too weak.

If you take more Pangrol 25 000 than you should

Drink a lot of water afterwards and speak to your doctor or pharmacist. Extremely high doses of pancreas powder, particularly 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 25 000

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

If you stop taking Pangrol 25 000

If you end treatment with Pangrol 25 000 early, or if you interrupt treatment, then it is expected that your symptoms may return. Contact your doctor.

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

OGYI/20111/2014

OGYI/20115/2014

4. Possible side effects

Like all medicines, this medicine 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 25 000 any longer and go to your doctor at once if possible. He will then decide on the further treatment.

Very rare side effects (may affect fewer than 1 user in 10,000)

- diarrhoea, abdominal discomfort, abdominal pain, nausea, vomiting
- Immediate-type allergic reactions, for example skin rash, nettle rash (urticaria), sneezing, flowing tears, breathlessness due narrowing of the airways (bronchospasm), shortness of breath
- allergic reaction of the digestive tract
- Narrowing of the small intestine/appendix region and the ascending sections of the large intestine has been described in patients with cystic fibrosis after administration of high doses of pancreas powder. This narrowing may potentially lead to a bowel obstruction (see Section 2. "Warnings and precautions").

If unusual stomach and gastro-intestinal discomfort or changes in the complaints occur, you should have these examined by your doctor as a precaution in order to rule out the possibility of damage to the intestines. This particularly concerns patients taking over 10,000 units lipase per kg body weight daily.

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

- 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.

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 national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pangrol 25 000?

Keep this medicine out of sight and reach of children.

Do not use Pangrol 25 000 after the expiry date which is stated on the outer carton and the label after (Exp:). The expiry date refers to the last day of that month.

Do not store above 25 °C.

Stable for 6 months after first opening.

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.

6. Contents of the pack and other information

What Pangrol 25 000 contains?

OGYI/20111/2014

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- The active substance is porcine pancreas powder
1 hard capsule with gastro-resistant minitablets contains 356.1 mg porcine pancreas powder:
Lipase activity 25,000 Ph. Eur. Units/capsule
Amylase activity not less than 22,500 Ph. Eur. Units/capsule
Protease activity not less than 1,250 Ph. Eur. Units/capsule

- The excipients are:

Minitablets core:

Hydrogenated castor oil, colloidal anhydrous silica, magnesium stearate, croscarmellose sodium, microcrystalline cellulose

Minitablets shell:

Methacrylic acid - ethyl acrylate copolymer (1:1) 30 % dispersion, talc, triethyl citrate, simethicone emulsion 30 % (dry), purified water.

Capsule shell:

Red iron oxide (E 172), yellow iron oxide (E 172), indigo carmine (E 132), quinoline yellow (E 104), titanium dioxide (E 171), gelatine

What Pangrol 25 000 looks like and contents of the pack

Pangrol 25 000 elongated capsules size 0, body light orange opaque and cap yellowish green opaque with light brown, shiny, homogeneous minitablets.

50, 100, 200 hard capsules are filled into polypropylene (PP) bottles that are sealed with a polyethylene (PE) closure with desiccant. One container is in an outer carton.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Berlin-Chemie AG (Menarini Group)
Glienicke Weg 125, 12489 Berlin
Germany

Produced with EURAND Minitabs® Technology

A készítményhez kapcsolódó további kérdéseivel forduljon a forgalomba hozatali engedély jogosultjának helyi képviselőjéhez:

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OGYI-T-7601/01 50 pcs.
OGYI-T-7601/02 100 pcs.
OGYI-T-7601/03 200 pcs

This leaflet was last approved in: October 2014

OGYI/20111/2014
OGYI/20115/2014