Package leaflet: information for the user

Pangrol 10000 V gastro-resistant capsules, hard
Pancreatic powder

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet as 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. Do not pass it on to others. It may harm them
- (even if their symptoms 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. See section 4.

What is in this leaflet:

1. What Pangrol is and what it is used for

Pangrol is a medicinal product containing pancreatic enzymes.

Pangrol is used to treat a deficiency of pancreatic production and secretion of digestive enzymes with associated digestive disorders.

2. What you need to know before you take Pangrol

Do not take Pangrol:

- If you are allergic (hypersensitive) to pancreas powder, to pork or any of the other ingredients of this medicine (listed in section 6).
- If you have acute inflammation of pancreas or exacerbation of chronic pancreatitis with severe symptoms.
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Warnings and precautions
Talk to your doctor or pharmacist before taking Pangrol**.**
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Intestinal obstruction is a known complication in patients with cystic fibrosis. Talk to your doctor before using Pangrol if you think that you have bowel obstruction – like symptoms (e.g. severe, spasmodic or constant, slashing, spreading threw the whole abdomen abdominal pain, with nausea, vomiting and sluggish and lacking bowel function)**.**
Pangrol contains an active enzyme which may affect the mucous membrane (cause ulcers) if released in the mouth, e.g. on chewing the capsule. Therefore, Pangrol should be swallowed whole, or if the gastro-resistant hard capsule has to be opened, all of its contents should be swallowed immediately (see section „How to take Pangrol“).

Children and adolescents
There are currently no data available.

Other medicines and Pangrol
Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including those obtained without prescription.

Medicines containing pancreatic powder may inhibit folic acid absorption (the passing of folic acid into circulation). Therefore, folic acid may have to be co-administered.

Concomitant use of Pangrol with acarbose and miglitol, antihyperglycemic agents (oral drugs for diabetes), may reduce the effect of the latter agents.

Pregnancy and lactation
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.
There are no adequate data on the use of Pangrol in pregnancy.
Only insufficient data from animal-experienced studies exist regarding pregnancy, development of the unborn child, delivery and development of the child after birth. No risk to humans has been established. If you are pregnant or you are breast-feeding, you should not take Pangrol unless your doctor feels taking it to be absolutely necessary.

Driving and operating machines
Pangrol has no or negligible influence on the ability to drive and use machines.

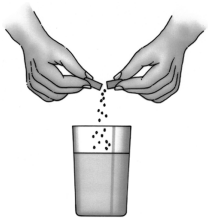
3. How to take Pangrol

Always take this medicine exactly as your doctor has instructed you. If you have any doubts, consult your doctor or pharmacist.

Pangrol is used to objectively achieve and maintain a normal body weight, normal bowel movement frequency and normal faecal consistency.

The dose depends on the severity of pancreatic dysfunction and digestion of the medicinal product used. The usual recommended dose is 20000-40000 lipase units per meal.
If not indicated otherwise, the recommended dose is 2 to 4 Pangrol gastro-resistant hard capsules (equivalent to 20000-40000 lipase units) per meal. If necessary, the dose may be higher. The dose should be increased only under medical supervision and after evaluating symptoms (e.g. faecal fats and severity of abdominal pain).
The daily dose of 15000-20000 lipase units/kg body weight should not be exceeded.

How and when Pangrol should be taken
Pangrol should be swallowed whole with a sufficient amount of liquid during a meal.
For patients unwilling to swallow the gastro-resistant hard capsule, its contents can be emptied into container (e.g. a glass) with a small amount of liquid and swallowed all immediately. Compound of medicinal product and liquid should not be kept.



How long Pangrol should be taken
The duration of treatment should be determined by a doctor.

If you consider the effect of Pangrol to be too strong or too weak, consult your doctor or pharmacist.

If you take more Pangrol than you should?

Drink a lot of water afterwards and speak to your doctor or pharmacist or nurse. 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
Do not take a double dose to make up for forgotten individual doses.

After you stop taking Pangrol
If you stop taking Pangrol too early or discontinue the drug, you will not achieve the expected effect of the drug or your digestion will worsen again.

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

4. Possible side effects

Like all medicines, this medicine may cause side effects in some people.

Very rare side effects (may affect up to 1 in 10,000 people)
In patients with cystic fibrosis, narrowing of the lower sections of the intestines have been described following administration of high doses of Pangrol 10000V.
Allergic reactions of the digestive tract (such as diarrhoea, gastric complaints and nausea).
Immediate-type allergic reactions, for example skin rash, nettle rash (urticaria), sneezing, flowing tears, breathlessness due narrowing of the airways (bronchospasm), shortness of breath.

Frequency of side effects not known (frequency cannot be estimated from the available data)
In patients with cystic fibrosis, especially when high doses of Pangrol 10000V are taken, increased uric acid excretion with the urine may occur. Uric acid excretion with the urine should therefore be checked in these patients in order to avoid the formation of uric acid stones.

Reporting of side effects
If you get any side effects, even not listed in this leaflet, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to the State Medicines Control Agency under the Ministry of Health free phone 8 800 73568 or filling the form on the website www.vvkt.lt and sending it to State Medicines Control Agency under the Ministry of Health in one of these methods: written form (adress Žirmūnų g. 139A, LT-09120 Vilnius), free fax 8 800 20131, email NepageidaujamaR@vvkt.lt, also through State Medicines Control Agency under the Ministry of Health website (adress http://www.vvkt.lt).

5. How to store Pangrol

Keep this medicine out of the sight and reach of children.
Do not store above 25°C.

Do not use this medicine after the expiry date shown on the bottle label and carton. The drug can be used until the last day of the indicated month.
The medicine should be used within 6 months after opening the bottle for the first time.

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. Further information

Composition of Pangrol

- The active ingredient is pancreatic powder. One gastro-resistant hard capsule contains 98.3 mg - 178.6 mg pancreatic powder (pancreatin produced from porcine pancreatic) with minimum activity equivalent to 10000 lipase units, 9000 amylase units, 500 protease units according to the European Pharmacopeia.
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- Excipients:
- The capsule contains: hydrogenated castor oil, colloidal anhydrous silica, magnesium stearate, croscarmellose sodium, microcrystalline cellulose, simeticone emulsion 30% (dry), methacrylic acid-ethyl acrylate (1:1) 30% dispersion, talc, triethylcitrate. Composition of the capsule shell: gelatine, titanium dioxide (E 171), yellow iron oxide (E 172), red iron oxide (E 172), indigo carmine (E 132), quinoline yellow (E 104).

Pharmaceutical form of Pangrol and contents of package
Pangrol 10000 V gastro-resistant hard capsules with a light orange opaque body and yellowish green opaque cap. Each capsule contains light brown bright homogeneous minitablets.

Package
Plastic bottle contains 20, 50, 100 or 200 gastro-resistant hard capsules and desiccant.
Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturer
Marketing authorisation holder
BERLIN-CHEMIE AG (MENARINI GROUP)
Glienicker Weg 125
D-12489 Berlin
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Manufacturer
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Germany

For any further information about this medicinal product, please contact the local representative of the marketing authorisation holder.

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This package leaflet was last revised on 2017-01-03.

Detailed information on the medicine is available at the website http://www.vvkt.lt/ of the State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania.