

PATIENT INFORMATION LEAFLET

PANZOL 40 mg Enteric Coated Tablet
It is taken orally.

- **Active substance:** Each tablet contains pantoprazole sodium sesquihydrate equivalent to 40 mg pantoprazole
- **Excipients:** Mannitol (E421), calcium carbonate (E170), crospovidone, vinylpyrrolidone-vinyl acetate copolymer, sucrose stearate (E473), calcium stearate, hydroxypropyl methyl cellulose (E464), titanium dioxide (E171), triacetin (E1518), methacrylic acid copolymer, talc (E553b), triethyl citrate (E1505), colloidal anhydrous silica (E551), sodium bicarbonate (E500), yellow iron dioxide (E172), sodium lauryl sulfate

Read this LEAFLET carefully before you start to use the medicine. It contains important information for you.

- **Keep this leaflet.** You may need to read it again.
- **If you have any further questions, consult your doctor or pharmacist.**
- **This medicine is prescribed for you personally. Do not give it to others.**
- **During the use of this medicine, when you visit a doctor or a hospital, tell your doctor that you are using this medicine.**
- **Follow the directives in this leaflet strictly. Do not use higher or lower dose of the medicine than the one recommended to you.**

In this patient information leaflet:

1. **What PANZOL is and what it is used for**
2. **What you need to know before you take PANZOL**
3. **How to take PANZOL**
4. **Possible side effects**
5. **How to store PANZOL**

Topics are included.

1. What PANZOL is and what it is used for

- PANZOL is put into use in tablets (enteric coated) coated with a special substance that prevents the dissolution of the drugs in stomach. Each tablet contains 40 mg pantoprazole (as pantoprazole sodium sesquihydrate) as active substance.
- Pantoprazole, active substance of PANZOL, is included in a drug group named as "proton pump inhibitor". It shows its effect by minimizing the amount of acid produced in your stomach. It is used for the treatment of diseases in the stomach and intestines related with the acid.
- PANZOL is put on the market in blister packages containing 14 and 28 tablets which are yellow colored, oval, biconvex and unscored.

PANZOL is used:

- **In adults and children older than 12 years:**
 - In the treatment of reflux esophagitis (an inflammation of your esophagus (the tube which connects your throat to your stomach) accompanied by the regurgitation of stomach acid
 - In the treatment of gastro-esophageal reflux disease (GERD)

In adults:

- In the treatment of duodenal and gastric (stomach) ulcers caused by a bacteria called *Helicobacter pylori* (*H.pylori*). It is administered with two proper antibiotics to eradicate this bacteria and decrease repetition of these ulcers
- In the treatment of peptic ulcer (duodenal and gastric ulcer)
- In the treatment of Zollinger Ellison Syndrome (tumors in pancreas, secreting hormone causing too much acid in stomach) and in other conditions causing too much acid secretion in the stomach.

2. What you need to know before you take PANZOL

DO NOT TAKE PANZOL in following situations

If you are allergic (hypersensitivity) to pantoprazole active substance or any of the other ingredients of PANZOL, benzimidazoles (medicines used for fungal diseases), you are allergic to any of the other drugs containing proton pump inhibitor, do not use PANZOL.

TAKE PANZOL WITH SPECIAL CARE in following situations

- If you have severe hepatic impairment, if you had a problem with your liver, report to your doctor. During the treatment with PANZOL, especially when it is used for a long time, your doctor will check your liver enzymes regularly. In case of an increase in liver enzymes, PANZOL usage should be stopped.
- If sources of B12 vitamin in your body have decreased or if you possess risk factors for vitamin deficiency, you should be careful. Pantoprazole, like all other gastric acid inhibitors, may minimize the absorption of B12 vitamin.
- If you have been using PANZOL for more than 1 year, tell your doctor. In that case, probably your doctor will keep you under regular observation. If you recognize new and extraordinary symptoms, you should tell your doctor about these.
- Treatment with PANZOL may suppress the symptoms related with the cancer and eventually delay the diagnosis. Therefore, before PANZOL treatment, your doctor may run some tests to ensure that you do not have cancer. If your symptoms continue during your treatment, further examinations may be necessary.

Stop taking PANZOL if you experience one of the conditions below and inform your doctor or apply to the emergency department of the nearest hospital IMMEDIATELY:

- **Very serious allergic diseases (rare):** Swelling on tongue and/or throat, swallowing difficulty/ indigestion, rash (urticaria), difficulty in breathing, allergic swelling on face (Quincke disease/ angioedema), dizziness accompanied by sweating and very fast heart beating.
 - **Very serious skin diseases (unknown frequency degree):** Fulminant, widespread, bubbling, painful rashes on the skin, deterioration in general health status, irritation on eyes, nose, mouth/lips and genital organs (mild bleeding) (these may be symptoms of severe skin reactions like Stevens Johnson Syndrome, Erythema Multiforme and Lyell Syndrome) and sensitivity to light.
 - **Other very serious diseases (unknown frequency degree):** Yellowing on the skin or white parts of the eyes (severe damage in liver cells, jaundice) or growth in kidneys accompanied by fever, urticaria, painful urine and with back pain (severe nephritis).
- All of these are very serious side effects.
If you have one of these, it means you have a serious allergy against PANZOL. You may need emergency medical intervention or hospitalization.

If you recognize any of the below, tell your doctor:

- **Uncommon** (May be observed between 1 to 10 in 1000 patients)
Headache, dizziness, diarrhea, not feeling good, vomiting, stomach bloating and gas, constipation, dryness of the mouth, abdominal pain, allergic reactions like erythema, itchiness and skin rash, weakness, sleep disorders.
- The risk of fracture on hips, wrists or spine increases particularly in patients who use proton pump inhibitor like pantoprazole for longer than one year. If you have osteoporosis disease or you use corticosteroids increasing the osteoporosis risk, tell your doctor.
- **Rare** (May be observed between 1 to 10 in 10000 patients)
Deterioration or complete loss of tasting, visual disorders like blurred vision, rash (urticaria), joint pain, muscle pains, gaining/losing weight, increase of body temperature, high fever, swelling on hands and feet (peripheral edema), allergic reactions, depression, breast augmentation in men (gynecomastia).
- **Very rare** (May be observed in less than 1 in 10000 patients)
Orientation disorder.
- **Unknown** (It cannot be estimated from the available data):
Seeing or hearing things that do not exist especially in disposed patients (hallucination), loss of time and space harmony and wooziness (confusion), decrease in blood sodium level (hyponatremia). If you are using PANZOL for more than three months, it is possible that magnesium levels in your blood decrease. Symptoms of decrease in magnesium level (hypomagnesemia) are fatigue, involuntary myotonia, orientation disorder, spasms, dizziness and increase in the pulse. Decrease in magnesium level may also cause decrease in potassium and calcium levels in your blood. Your doctor may require regular tests to monitor the magnesium levels in your blood.

Side effects that can be determined by blood tests:

- **Uncommon** (May be observed between 1 to 10 in 1000 patients)
Increase in liver enzymes.
 - **Rare** (May be observed between 1 to 10 in 10000 patients)
Increase in bilirubin level in blood, increase in triglyceride (fat) level in blood, sudden decrease (accompanied by high fever) in number of white blood cells (leucocyte).
 - **Very rare** (May be observed in less than 1 in 10000 patients)
Decrease in number of blood cells (blood platelets) ensuring coagulation in blood (this case may cause more bleeding than normal), decrease in number of white blood cells (leucocyte) (this case may cause more frequent infections). Abnormal decrease in all of the red blood cells (erythrocyte), white blood cells (leucocyte) and blood cells ensuring the coagulation (blood platelets) may be observed.
- If you encounter any side effect that is not included in this patient information leaflet, inform your doctor or pharmacist.

5. How to store PANZOL

Keep PANZOL out of the sight and reach of children and in its original package.
Store at room temperature below 25°C in a dry place by protecting from light.

Use in line with the expiry date.

Do not use PANZOL after the expiry date on the package.

If you notice defects in product and/or packaging, do not use PANZOL.

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- If you have osteoporosis disease, tell your doctor. Like all other proton pump inhibitors, when PANZOL is used in high doses and for a long time (more than 1 year) in patients with osteoporosis, in elder patients and in cases of other risk factors, it may increase the risk of fracture in hips, wrists and spine. In that case, your doctor may recommend you to use PANZOL in lower doses or for shorter time.
- If you were diagnosed with hypomagnesemia (low magnesium mineral level in your blood) before, tell your doctor. Like all other proton pump inhibitors, PANZOL may cause hypomagnesemia after a treatment for at least 3 months (generally, more than 1 year). In that case, your doctor may decide that you should take magnesium supplement or continue PANZOL treatment for a shorter time. In case you feel that your heart beats abnormally fast, slow or arrhythmic during your PANZOL treatment, if you have fatigue or dizziness feeling, muscle spasm or seizure, tell your doctor. These symptoms may be related with hypomagnesemia. Furthermore, if there are any other medicines you are taking, tell them to your doctor as well. Hypomagnesemia may cause decrease in potassium and calcium levels in the blood. If your doctor deems necessary, the magnesium level in your blood can be monitored regularly.
- If you are undergoing neuroendocrine tumor diagnosis tests, tell your doctor, since like all other proton pump inhibitors, PANZOL may affect the results of these tests. Like all other proton pump inhibitors, PANZOL may increase the number of some bacteria that normally exist in upper gastrointestinal tract and therefore the risk of infection (*Salmonella* and *Campylobacter*) even a little.
- If it is used to prevent the ulcers triggered by the non-steroidal anti-inflammatory agents (painkiller not in the form of steroid, inflammation inhibitor) (NSAI), PANZOL should be limited to the patients requiring continuous NSAI medication with high side effect risk in gastrointestinal system (for example; over age 65, with history of ulcer or gastric bleeding).
- If you are taking anticoagulants or blood thinners like warfarin and phenprocoumon, you may need to have further tests.
- If you notice one of the following situations, consult your doctor IMMEDIATELY:
 - Unexpected weight loss,
 - Recurrent vomiting,
 - Dysphagia,
 - Hematemesis,
 - Looking pale and feeling weak (anemia)
 - Blood in stool
 - Severe and continuous diarrhea

If these cautions are valid for you, even for a period in the past, consult your doctor.

Taking PANZOL with food and drinks
PANZOL should be swallowed 1 hour before meal as whole with an amount of water without chewing or breaking.

Pregnancy
Consult your doctor or pharmacist before using the medicine.
There is no sufficient data on use of pantoprazole in pregnancy. If you are pregnant or you think that you may be pregnant, but, in case your doctor thinks that estimated benefit of the medicine is more than the risk of damaging your unborn baby, then you should use pantoprazole.

Breast-feeding
Consult your doctor or pharmacist before using the medicine.

It is reported that pantoprazole passes into breast milk. It should only be used in nursing mothers in case the benefit of the medicine to the mother is more than the risk of damaging the baby.

Driving and using machines
If you experience dizziness and visual disorders, do not drive and use machine.

Important information about some of the excipients of PANZOL
PANZOL contains a sugar named sucrose. If you have been told by your doctor previously that you have intolerance to some sugars (your body shows negative reaction to some sugars), consult your doctor before taking this medicinal product.

This medicinal product contains sodium less than 1 mmole (23 mg) in each tablet; so basically "it does not contain sodium".

This medicinal product contains mannitol less than 10 g (29.5 mg) in each tablet; so laxative effect is not expected.

Taking with other medicines
• Pantoprazole may decrease the absorption and minimize the effects of medicines which are used to prevent fungal infections like ketoconazole, itraconazole and posaconazole, absorption of which depends on the acid level in the stomach (pH) and some anti-cancer drugs like erlotinib.

• Proton pump inhibitors decrease the absorption of the medicines used in the treatment of HIV (AIDS) like atazanavir. Proton pump inhibitors, including pantoprazole, are not recommended to be used with atazanavir.

• Pantoprazole is metabolized in the liver. Similarly, there may be interaction between pantoprazole and other medicines metabolized in the liver. In addition, special tests are made with the following drugs and no interaction with clinical importance is observed.

- Carbamazepine (epilepsy and mood disorder drug)
- Diazepam (used to prevent anxiety disorder)
- Nifedipine (used in the treatment of high blood pressure)
- Glibenclamide (antidiabetic)
- Birth control pills (containing levonorgestrel and ethinyl estradiol)

• If you are using a drug assisting blood clotting (like phenprocoumon/warfarin), it is recommended to monitor the blood clotting values after starting and termination of pantoprazole treatment and during the irregular administration.

• No interaction is observed with antacids. Antacids are used to reduce the gastric acid immediately and they are generally in chewing tablet or syrup form.

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If you are using a prescribed or non-prescribed medicine currently, or have used recently, inform your doctor or pharmacist about these.

3. How to take PANZOL

- **Instructions for proper use and dose/dosing intervals:**

In adults and children older than 12 years:
In the treatment of reflux esophagitis (inflammation of esophagus as a result of escaping of foods and acid from the stomach to esophagus) and related symptoms (for example, pain and burning on chest, regurgitation of stomach acid to esophagus, pain during swallowing):

Recommended dose is 1 PANZOL tablet per day. Your doctor may recommend 2 PANZOL tablets per day. Treatment period is usually 4-8 weeks. Your doctor will inform you that how long your treatment with PANZOL will continue.

In adults:

In the treatment of duodenal and gastric (stomach) ulcers caused by a bacteria called *Helicobacter pylori* (*H.pylori*), it is administered in combination with proper two antibiotics.

Recommended dose is 1 PANZOL tablet twice per day in combination with two of antibiotics such as amoxicillin, clarithromycin and metronidazole (or tinidazole). First tablet should be taken 1 hour before the breakfast and second tablet should be taken 1 hour before the dinner. Treatment period is usually 1-2 weeks. Follow your doctor's recommendations and read the patient information leaflets of these antibiotics.

In the treatment of gastric ulcer and duodenal ulcer:

Recommended dose is 1 PANZOL tablet per day. Your doctor may recommend you to take 2 PANZOL tablets per day. Treatment period for gastric ulcer is usually 4-8 weeks and for duodenal ulcer it is usually 2-4 weeks. Your doctor will inform you that how long your treatment with PANZOL will continue.

In the long term treatment of Zollinger Ellison Syndrome and in other conditions causing too much acid secretion in the stomach:

Recommended initial dose is usually 2 PANZOL tablets per day.
2 tablets are taken at the same time 1 hour before the dinner. Your doctor will adjust the dose later according to acid producing of your stomach. If your doctor recommends you to take more than 2 tablets per day, tablets are taken as two times in a day.

If your doctor recommends you to take more than 4 tablets, your doctor will tell you when you will stop taking this medicine.

Administration route and method:

PANZOL should not be chewed or broken; it should be swallowed as a whole with an amount of water 1 hour before meal.

Various age groups:

Pediatric use:
It should not be administered to the children under 12 years of age.

Geriatric use:

PANZOL may be used in elder patients without dose adjustment.

Special administration conditions:

Renal failure:
If you have kidney function disorder and severe or middle level of liver problems, do not take PANZOL for *H. pylori* treatment.

Liver failure:

20 mg pantoprazole dose per day should be not exceeded in the patients with severe liver impairment. If you have the impression that the effect of PANZOL is either very potent or very weak, talk to your doctor or pharmacist.

If you take more PANZOL than you should:

There are no known symptoms for overdose.

If you take more PANZOL than you should, talk to a doctor or a pharmacist.

If you forget to take PANZOL:

If you forget to take your medicine, do not take double doses to make up the missed dose. Continue your treatment with next dose, according to the dosage regime that your doctor deemed suitable.

Do not take double doses to make up the missed dose.

Possible effects after the discontinuation of PANZOL treatment:

Your doctor will inform you that how long your treatment with PANZOL will continue. Do not stop the treatment earlier because the symptoms of your disease may come back or get worse.

4. Possible side effects

As with all drugs, there may be side effects in the individuals who are sensitive to any of the ingredients of PANZOL.

Side effects are classified according to the prevalence given below.

Very common : May be observed in at least 1 of 10 patients.

Common : May be observed between 1 to 10 in 100 patients.

Uncommon : May be observed between 1 to 10 in 1000 patients.

Rare : May be observed between 1 to 10 in 10000 patients.

Very rare : May be observed in less than 1 in 10000 patients.

Unknown : It cannot be estimated from the available data.