

PATIENT INFORMATION LEAFLET

PROTECH ENTERIC-COATED TABLETS, 40 mg

Orally taken.

- **Active Pharmaceutical Ingredient:** 40 mg pantoprazole equivalent in each tablet 45,10 mg pantoprazole sodium sesquihydrate
- **Excipients:** Sodium carbonate anhydrous, Mannitol, Crospovidone, Povidone K90, Quinoline yellow, Calcium stearate, Hydroxypropyl methyl cellulose, Titanium dioxide , Talc, Polyethylene glycol 400, Sodium lauryl sulfate, Eudragit L-100/55 , Triethyl citrate, Colloidal silica anhydrous, Sodium bicarbonate

Read all of this LEAFLET carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others.
- During the use of this medicine, tell your doctor when you go to a doctor or hospital that you are using this medicine.
- Please keep strictly to what is written in these instructions. Do not use high or low doses other than the recommended dose for the medication.

In this leaflet:

- 1. What PROTECH is and what it is used for?**
- 2. Things to be considered before you take PROTECH**
- 3. How to use PROTECH?**
- 4. What are the possible side effects?**
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Headings included.

1. What PROTECH is and what it is used for ?

- PROTECH is offered in the form of tablets (enteric coated tablets) coated with a special substance that prevents the drug from dissolving in the stomach. Each tablet contains 40 mg pantoprazole (pantoprazole sodium sesquihydrate) as the active ingredient.
- Pantoprazole, an active ingredient of PROTECH, is included in a group of drugs called “Proton Pump inhibitor”. It shows its effect by reducing the amount of acid produced in your stomach. It is used in the treatment of the relationship with acid disorders of the stomach and intestines.
- PROTECH is marketed in blisters with 14 or 28 tablets. Blister tablets are round shaped and yellow in color.

PROTECH:

In adults and adolescents 12 years of age and above:

- In gastroesophageal reflux disease (GERD: Stomach content escaping back to the esophagus),

Adults:

- In order to eliminate this bacterium in duodenal (duodenal) and gastric (gastric) ulcers caused by a bacterium named Helicobacter pylori (H. pylori), and thus to reduce the recurrence of these ulcers, together with two appropriate antibiotics,
- In peptic ulcer treatment (duodenal ulcer and gastric ulcer),
- Zollinger Ellison Syndrome (pancreatic tumors that produce hormones that cause excessive acid formation) and other conditions that cause excessive gastric acid secretion.

2. Things to be considered before you take PROTECH

Do not take PROTECH in the following conditions:

If;

- You have allergy (hypersensitivity) to the active substance pantoprazole or one of the adjuncts in the compound of PROTECH®, benzimidazoles (drugs used for fungal diseases)
- You are allergic to medicines containing proton pump inhibitors,

Do not use PROTECH.

Use PROTECH with cautions in the following conditions.

IF;

- If you have severe liver disorder, if you have any problems with your liver, report to your doctor.. During treatment with PROTECH, especially in long -term use, your doctor will regularly check your liver enzymesIf the liver enzymes increase, the use of PROTECH should be discontinued
- You should be careful if you have risk factors in terms of vitamin B12 stores in your body or in terms of vitamin B12 deficiency. Pantoprazole, like all other stomach acid reducing drugs, can reduce the absorption of vitamin B12.
- Tell your doctor if you have been using PROTECH for more than 1 year. In this case, your doctor will probably keep you under regular observation. If you see new and unusual symptoms, you must say that when you go to your doctor.
- You use HIV protease inhibitors such as Atazanavir (for the treatment of HIV infection) with pantoprazole, consult your doctor for advice.
- The use of a proton pump inhibitor such as pantoprazole, especially for more than one year, may increase your risk of hip, wrist or spine fracture. Tell your doctor if you have bone resorption (osteoporosis) or use corticosteroid (which can increase the risk of osteoporosis).
- If you have been using PROTECH for more than three months, magnesium levels in your blood may decrease. Low magnesium levels can be manifested by fatigue, involuntary muscle contractions, orientation disorder, convulsions (shaking), dizziness, increased heart rate. If you experience any of these symptoms, please tell your doctor immediately. Low magnesium levels may also lead to a decrease in potassium or calcium levels in your blood. Your doctor may decide to perform regular blood tests to monitor magnesium levels.
- Alcohol use should be avoided during treatment.
- If you have had a skin reaction after treatment with a drug -like drug that reduces stomach acid,
- Proton pump inhibitors can cause rashes very rarely in the sun exposed to the sun. Especially if there are rashes in the sun exposed to the sun and there are accompanying joint pain, urgent medical attention and stop using PROTECH. If a proton pump

inhibitor treatment was developed, the risk of other proton pump inhibitors of similar structure and rashes increased if these rashes are developed.

- Tell your doctor if you have a neuroendocrine tumor diagnostic tests, because all proton pump inhibitors, such as PROTECH may affect the outcome of these tests.
- All proton pumps, such as inhibitors, may increase the number of some bacteria that normally exist and thus the risk of infection (Salmonella and Campylobacter or C differential) in the upper gastrointestinal tract.
- PROTECH is used to prevent ulcers triggered by non-steroidal anti-inflammatory drugs (NSAIDs), the use of PROTECH may require continuous use of NSAIDs and a high risk of developing adverse events in the gastrointestinal tract Age 65 or older, history of ulcer or stomach bleeding).
 - If you use drugs that intensify or thin blood such as warfarin and phenprocoumon, you may need to have advanced controls.
 - You will have a specific blood test (chromogranin A).
 - Tell your doctor **IMMEDIATELY** if you notice any of the following symptoms:
 - An unintentional loss of weight
 - Repeated vomiting
 - Bloody vomiting; it looks like a dark brown wire in vomiting
 - Blood in the feces; the appearance can be black or tar liked
 - Hearing difficulty or pain while swallowing,
 - You look pale and feel weak (anaemia)
 - Chest pain
 - Stomache ache
 - Severe and/or persistent diarrhoea,

With PROTECH, treatment may suppress cancer -related symptoms and ultimately delay the diagnosis. Therefore, before PROTECH treatment, your doctor can make you some tests to make sure you are not having cancer patients. If your symptoms continue during your treatment, other examinations may be required.

If you have been using PROTECH for more than 1 year, your doctor will probably keep you under regular observation. If you see new and unusual symptoms, you must say that when you go to your doctor.

If these warnings are valid for you, even in any period of the past, please consult your doctor.

Use of PROTECH with food and beverages:

PROTECH should be swallowed 1 hour before meals, without chewing or breaking, and with some water as a whole.

Pregnancy

Ask your doctor or pharmacist for advice before taking medicine.

There are no adequate data from the use of PROTECH in pregnant women. If you are pregnant, or think you may be pregnant you should use this medicine only if your doctor considers the benefit for you greater than the potential risk for your unborn child or baby.

If you notice that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breast-feeding

Ask your doctor or pharmacist for advice before taking medicine.

Excretion into human milk has been reported. If you are breast-feeding, you should use this medicine only if your doctor considers the benefit for you greater than the potential risk for your baby.

Driving and using machines

PROTECH has no effect on the ability to use vehicles and machinery or is negligible.

If you are experiencing dizziness and visual impairments, do not use vehicles or machinery.

Important information about some excipients contained in PROTECH

This medical product contains 6.7 mg sodium on each tablet. This situation should be considered for patients with a controlled sodium diet.

This medical product contains less than 10 grams (71.47 mg) mannitol with each tablet, so it is not expected to have laxative effects.

Usage with other medicines

PROTECH may disrupt the effectiveness of other drugs, so tell your doctor if you take the following medications;

- Pantoprazole may weaken its efficacy by reducing the absorption of drugs intended to prevent fungal infections such as ketoconazole, itraconazole and posaconazole, or certain cancer drugs, such as erlotinib, whose absorption is dependent on the acid level (pH).
- If you use warfarin and phenprocoumon that affect blood thickening or thinning, you may need more control.
- Drugs used in the treatment of HIV (AIDS) infection such as Atazanavir,
- Methotrexate (Rheumatoid arthritis, used in the treatment of psoriasis and cancer) - If you receive metotrexate, pantoprazole can increase the level of methodrexate in the blood, your doctor can temporarily stop the PROTECH treatment,
- If you use Fluvoxamine (used in the treatment of depression and other psychiatric diseases), your doctor may reduce the dose of pantoprazole,
- Rifampicin (used in the treatment of infections),
- Yellow weighing (hypericum perforatum) (used to treat mild depression).

If you are currently using any medication with or without a prescription or you have recently used it, please inform your doctor or pharmacist.

3. How to use PROTECH?

Method of Administration:

PROTECH should be swallowed 1 hour before meals, without chewing or breaking, and with some water as a whole.

Instructions for proper use and dose / application frequency:

In adults and adolescents 12 years of age and above

In the treatment of reflux esophagitis (escape of food and acid from the stomach) and related symptoms (eg, burning and pain in the torso, retraction of the stomach acid to the eating habit, pain during swallowing):

The recommended dose is one tablet PROTECH a day. Your doctor may recommend using 2 tablets PROTECH daily. Treatment time is usually 4-8 weeks. Your doctor will tell you how long to take your medicine.

In adults:

For the treatment of an infection with a bacterium called *Helicobacter pylori* in patients with duodenal ulcers and stomach ulcers in combination with two antibiotics:

Amoxicillin, clarithromycin and metronidazole (or tividazole) with two of the antibiotics proposed as a combined dose twice a day tablet PROTECH. The first tablet is taken 1 hour before breakfast and the second tablet is taken 1 hour before dinner. Treatment time is usually 1-2 weeks. Follow your doctor's suggestions and read the instructions for using these antibiotics.

Gastric ulcer and duodenal ulcer treatment

The recommended dose is one tablet a day. Your doctor may advise you to use 2 tablet. The treatment period for gastric ulcer is usually between 4 and 8 weeks. The treatment period for duodenal ulcers is usually between 2 and 4 weeks. Your doctor will tell you how long your treatment will last with PROTECH.

For the long-term treatment of Zollinger-Ellison syndrome and of other conditions in which too much stomach acid is produced

The recommended starting dose is usually two tablets a day.

Two tablets are taken 1 hour before meal. Depending on the acid production of the stomach, your doctor will then adjust the dose of your medicine. If your doctor advises you to use more than 2 tablets a day, the tablets are taken twice a day. If your doctor advises you to use more than 4 tablets a day, your doctor will tell you when to leave the medicine.

Different age groups:

Use in children:

It should not be used in children younger than 12 years.

Use in the elderly:

PROTECH can be used in the elderly without dose adjustment.

Special patient groups:

Kidney Failure:

If you have kidney dysfunction, do not use PROTECH for the treatment of *Helicobacter pylori*.

Liver Failure:

If you have heavy or moderate liver problems, do not use PROTECH for *Helicobacter pylori* treatment.

In patients with severe liver disorder, a daily dose of 20 mg of pantoprazole should not be exceeded.

If you have an impression that the effect of PROTECH is too strong or very weak, talk to your doctor or pharmacist.

If you take more PROTECH than you should

There are no known symptoms of overdose.

If you use more than you need to use PROTECH, talk to a doctor or pharmacist.

If you forget to take your PROTECH

If you forget to take your medicine, do not take double doses to compensate for the forgotten dose. Your treatment will not continue from the next dose, according to the dose schedule given by your doctor.

Do not take double doses to compensate for forgotten doses.

Effects that may occur when treatment with PROTECH® is terminated

Your doctor will tell you how long your treatment will last with PROTECH. Do not end treatment early because symptoms may return or your condition may worsen.

4. What is the possible side effects?

As with all medicines, there may be side effects in people who are sensitive to the substances contained in PROTECH.

Side effects are classified according to the following frequency ratings.

Very common : It can be seen in at least one of 10 patients.

Common: It can be seen less than one in 10 patients, but more than one in 100 patients.

Uncommon : It can be seen less than one in 100 patients, but more than one in 1,000 patients.

Rare : It can be seen less than one in 1,000 patients, but more than one in 10,000 patients.

Very rare: It can be seen in less than one in 10,000 patients.

Not known : It cannot be estimated from the available data.

If you get any of the following side effects, stop taking PROTECH and tell your doctor immediately, or contact the casualty department at your nearest hospital:

- **Very serious allergic disorders (seen rarely):** Swelling in the tongue and / or throat, swallowing/swallowing difficulties, hives (urticaria), difficulty breathing, allergic swelling (Quincke's disease/angioedema), dizziness with very fast heart rate and sweating.
- **Serious skin conditions (frequency not known):** Suddenly developing, widespread, in the form of bubbles, painful rashes, rapid deterioration of overall health, eye, nose, mouth/lip and sexual organ (slight blood) (these Steven Johnson Syndrome, Erythema multiforme and Lyell Syndrome symptoms of serious skin reactions such as symptoms of serious skin reactions may), sensitivity to light.
- **Other serious conditions (frequency not known):** Yellowing of the skin or whites of the eyes (severe damage to liver cells, jaundice) or fever, rash, and enlarged kidneys with painful urination and lower back pain (serious inflammation of the kidneys).

These are all very serious side effects.

If any of these are present in you, you have serious allergies to PROTECH. You may need to be admitted to an emergency medical intervention or hospital.

If you notice any of the following, tell your doctor:

- **Common:**

Benign polyps in stomach

- **Uncommon :**

Headache; dizziness; diarrhoea; feeling sick, vomiting; bloating and flatulence (wind); constipation; dry mouth; abdominal pain and discomfort; skin rash, exanthema, eruption; itching; feeling weak, exhausted or generally unwell; sleep disorders.

Hip, hand wrist or fracture in the spine

- **Rare:**

Distortion or complete lack of the sense of taste; disturbances in vision such as blurred vision; hives; pain in the joints; muscle pains; weight changes; raised body temperature; high fever; swelling of the extremities (peripheral oedema); allergic reactions; depression; breast enlargement in males (gynaecomastia)

- **Very Rare:**

Disorientation.

- **Not known:**

Especially in prone patients, seeing or hearing (hallucination), loss of time and space harmony and mind complexity (confusion); Blood fall at sodium level (hyponatremia), fall at blood magnesium level (See. "2. What to consider before using PROTECH"), The rash, probably with pain in the joints. If you are constantly diarrhea, tell your doctor to your doctor, because you may have intestinal inflammation (microscopic colitis).

Side effects identified through blood tests:

- **Uncommon:**

An increase in liver enzymes

- **Rare:**

An increase in bilirubin; increased fat levels in blood; sharp drop in circulating granular white blood cells (associated with high fever).

- **Very Rare:**

Decrease in the number of blood cells (platelets) that lead to blood clotting (which may cause more bleeding than normal); a decrease in the number of white blood cells (which may lead to more frequent infection); red blood cell, white blood cell, and blood cell (platelet) that provides clotting may all be at the same time abruptly reduced.

If you encounter any side effects that are not mentioned in this use instruction, inform your doctor or pharmacist.

5. How to store PROTECH?

Store PROTECH in places where it can not be seen, can not be accessed by children and in its packaging.

Store at room temperature below 25 ° C, in a dry place and protected from light.

Use in accordance with expiration dates.

Do not use PROTECH after the expiration date on the packaging.

Do not use PROTECH if you notice defects in the product and / or packaging.

Marketing Authorisation Holder

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Oğuzlar Mah. 1370. Sok. No: 7/3
06520 Balgat - Ankara / TURKEY

Manufacturer

Drogsan İlaçları San. ve Tic. A.Ş.
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This patient information leaflet is approved on 09.11.2022.

