

Toprazole®

Pantoprazole Tablets

Composition:

Each tablet contains Pantoprazole sodium sesquihydrate equivalent to Pantoprazole 40 mg.

Excipients: Mannitol, sodium carbonate, povidone, magnesium stearate, talc, hydroxy propyl methyl cellulose, sodium hydroxide, propylene glycol, methacrylic acid copolymer, triethylcitrate, simethicone, E171, E172.

Properties:

Pantoprazole sodium is a proton pump inhibitor, it inhibits the hydrogen-potassium adenosine triphosphatase enzyme system (H^+ , K^+ -ATPase), which is responsible for gastric acid secretion in the parietal cells of the stomach, and the inhibition is dose proportional.

Proton pump inhibitors are effective short term treatments for gastric and duodenal ulcer.

Pantoprazole exerts its full effect in an acidic environment ($PH < 3$), therefore, the complete pharmacological and therapeutic effect for pantoprazole is achieved only in the acid secreting parietal cells, its half life is approximately 1 hour, the absorption takes place in the small intestine.

The absolute systemic bioavailability of pantoprazole is approximately 77%, it is metabolized in the liver and the renal elimination represents the most important route of excretion (approximately 80%), and concomitant intake of food has no influence on the bioavailability.

Indications:

Toprazole is indicated for the short term treatment of duodenal ulcer, duodenal ulcer associated with helicobacter pylori infection, gastric ulcer and reflux esophagitis.

Contraindications:

Toprazole is contraindicated for patients with known hypersensitivity to any of its components.

Precautions:

Precautions should be taken in pregnancy and lactation because safety has not been established.

Safety and efficacy in children younger than 18 years of age have not been established.

Interactions with other drugs:

Pantoprazole may reduce or increase the absorption of drugs whose bioavailability is PH-dependent e.g. ketoconazole.

Concomitant administration of warfarin or phenprocoumon has no influence on its effect on coagulation factors.

There is no interaction between pantoprazole and antacids.

Warnings:

Care should be taken in patients with severely impaired liver function.

Pantoprazole is not indicated for mild gastro-intestinal complaints such as nervous dyspepsia.

Prior to treatment, the possibility of a malignant gastric ulcer or a malignant disease of the esophagus should be excluded, because the treatment with pantoprazole may alleviate the symptoms of malignant ulcers and can therefore delay diagnosis.

Dosage and Administration:

Duodenal ulcer: The recommended dosage is 40 mg pantoprazole once daily in the morning, and if associated with Helicobacter pylori infection it should be used in combination with appropriate antibiotics.

Gastric ulcer: The recommended dosage is 40 mg pantoprazole once daily in the morning for 4 to 8 weeks.

Reflux esophagitis: The recommended dosage is 40 mg pantoprazole once daily in the morning for 4 to 8 weeks.

Overdosage:

No overdosage symptoms have been reported.

Side Effects:

Headache, abdominal pain, diarrhea, constipation, flatulence. Allergic reactions such as: pruritus, skin rash, angioedema or anaphylactic shock.

Nausea, dizziness or disturbances in vision.

Peripheral edema, depression, fever or myalgia.

Consult your Pharmacist or Physician if any side effect is observed.

Pharmaceutical Precautions:

Keep at room temperature (15-30 °C).

Do not use beyond the expiry date or if the product shows any signs of deterioration.

Presentations:

Pack of 15 Tablets.

Pack of 30 Tablets.

Hospital packs are available.

® is a trademark.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Strictly follow the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists.



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