

Pantam Tablets

(Pantoprazole 40mg)

پانٹام
گولیاں
(پانٹوپرازول سوڈیم)

composition

1 gastro-resistant tablet contains; Pantoprazole Sodium sesquihydrate equivalent to 40 mg pantoprazole.

Mechanism

Selective proton pump inhibitor, substituted benzimidazole

Indications

- In combination with two appropriate antibiotics (see "Dosage" for the eradication of *Helicobacter pylori* in patients with peptic ulcers with the objective of reducing the recurrence of duodenal and gastric ulcer caused by this microorganism.
- Duodenal ulcer
- Gastric ulcer
- Moderate and severe cases of inflammation of the Oesophagus (reflux esophagitis)

Contraindications:

Pantam must not be used in combination treatment for eradication of *Helicobacter pylori* in patients with moderate to severe liver or kidney function disturbances since currently no clinical data are available on the efficacy and safety of Pantam in combination treatment of these patients. Pantam should generally not be used in cases of known hypersensitivity to one of the constituents of Pantam or of the combination parents,

Special warnings and precautions for use

Pantam is not indicated for mild gastrointestinal complaints, e.g. Nervous stomach. In the case of combination therapy, the prescribing information for the respective drugs must be observed. Prior to treatment with Pantam steps must be taken to ensure that gastric ulcer is not malignant, and that there is no malignant disease in the oesophagus, since the treatment would also alleviate the complaints associated with malignant disease and possibly delay establishment of the diagnosis. A diagnosis of reflux esophagitis should be confirmed by endoscopy. To date there has been no experience with treatment in children.

Pregnancy and lactation

Clinical experience in pregnant women is limited. There is no information on the excretion of pantoprazole into human breast milk. Pantam tablets should only be used when the benefit to the mother is considered greater than the potential risk to the foetus/baby

Interactions

Pantam may reduce the absorption of drugs whose bioavailability is pH-dependent (e.g. Ketoconazole) The active ingredient of Pantam is metabolized in the liver via the cytochrome P450 enzyme system. An interaction with other drugs of substances metabolized by the same enzyme system cannot be ruled out. However in targeted studies involving a range of such drugs and substances no clinically significant interactions were observed; studies have been carried out on carbamazepine, caffeine, diazepam, diclofenac, digoxin, ethanol, glibenclamide, metoprolol, nifedipine, phenytoin, theophylline, warfarin and an oral contraceptive. There were also no interactions with concomitant administered antacids. No clinically relevant interactions were observed with the respective antibiotics (clarithromycin, metronidazole, amoxicillin).

Dosage and administration

Unless otherwise prescribed, the following oral doses apply. Please follow these instructions, as otherwise there is the risk that the drug may not act properly. In cases of duodenal or gastric ulcer in which infection with *Helicobacter pylori* has been confirmed, the microorganism should be eradicated by combination treatment. Depending on the resistance pattern the following combinations are recommended.

- i) 2x1 Pantam gastro-resistant tablet/day
+2x1000 mg amoxicillin/day
+ 2x 500mg clarithromycin /day
- ii) 2x1 Pantam gastro-resistant tablet /day
+ 2x500mg metronidazole /day
+2x500 mg clarithromycin /day
- iii) 2x1 Pantam gastro-resistant tablet / day
+2 x 1000 mg amoxicillin / day
+2 x 500 mg metronidazole / day

For duodenal ulcer, gastric ulcer, and reflux-esophagitis. Generally, 1 Pantam gastro-resistant tablet daily. In individual cases the doses may be doubled (increase particularly when there has been no response to other medicines. In patients with severe liver impairment the dose has to be reduced to 1 tablet (40 mg pantoprazole) every other day. Further more, in these patients the liver enzymes should be monitored during Pantam therapy. In the case of a rise of the liver enzymes Pantam should be discontinued. The daily dose of 40mg Pantoprazole should not be exceeded in elder patients or in patients with impaired Kidney function. An exception is combination therapy for eradication of *Helicobacter pylori*, where also elderly patients should receive the appropriate pantoprazole dose (2x40 mg per day) during the 1-week treatment period.

Type and duration of treatment

Combination therapy for eradication of *Helicobacter pylori* infection usually lasts 7 days and can be extended to a maximum of 2 weeks. If after this time further treatment with Pantam is indicated to ensure that the ulcer heals completely, the dose recommendations for gastric and duodenal ulcers must be observed. In the majority of cases, a duodenal ulcer heals completely within 2 weeks. If a two-week treatment period is not sufficient, healing will be achieved in almost all cases with in a further 2 weeks. Gastric ulcers and reflux oesophagitis usually require a 4 week course of treatment, if this should be inadequate, healing will in most cases be achieved with in a further 4 weeks. Treatment should not exceed 8 weeks.

Instructions for use

Pantam gastro-resistant tablets must not be chewed or crushed and must be swallowed whole with water 1 hour before breakfast. In combination therapy for eradication for *Helicobacter pylori* infection the second Pantam tablet should be taken before the evening meal.

Overdosage

If you have taken too little Pantam or have forgotten to take it do not take the dose late, but continue with the next regular dose on your dosing schedule. Talk to your doctor if you want to interrupt or prematurely discontinue treatment with Pantam. In the case of overdosage with clinical signs of intoxication, the usual rules of intoxication apply.

Side Effects

Treatment with pantam can occasionally lead to headache, gastrointestinal, complaints such as upper abdominal pain, diarrhea, constipation or flatulence, as well as allergic reactions such as itching, skin rash and, in isolated cases, wheals, mucosal swelling or anaphylactic reactions including anaphylactic shock with typical symptoms such as dizziness, increases pulse rate or increased perspiration. There have been rare reports of nausea, dizziness, and visual disturbances (blurred vision).

Countermeasures

if you should experience side affects, notify your doctor so that he can decide what further measures are necessary. Keep away all medicines from children

Medical Precautions:

Store below 30 C, Protect from sun light and moisture.

Keep away all medicines from children

Use only on medical advice.



Manufactured By:
AIMS PHARMACEUTICALS
Plot # 291, Industrial Triangle, Kahuta Road,
Islamabad-Pakistan