121mm

182mm

Pantosel Tablet 40mg

(Pantoprazole Sodium)

پینٹوسیل ٹیبلیٹ ۴۰ ملی گرام

(پینٹوپرازول سوڈیم)

COMPOSITION:
Each enteric coated tablet contains:
Pantoprazole (as sodium).....40mg
(USP Specification)
(Product meets USP dissolution test 2)

INDICATIONS:
For the eradication of Helicobacter pylori in patients with peptic ulcers (in combination with two appropriate antibiotics and / or other drugs indicated for H.Pylori eradication)
Duodenal ulcer
Gastric ulcer
Moderate and severe reflex oesophagitis.

DOSAGE AND ADMINISTRATION:
Adults and adolescents 12 years of age and above
Reflux esophagitis
One tablet of Pantoprazole per day. In individual cases, the dose may be doubled (increase to 2 tablets Pantoprazole daily) especially when there has been no response to other treatment. A 4-week period is usually required for the treatment of reflux esophagitis. If this is not sufficient, healing will usually be achieved within a further 4 weeks.
Adults
Eradication of H. pylori in combination with two appropriate antibiotics In H. pylori positive patients with gastric and duodenal ulcers, eradication of the germ by a combination therapy should be achieved. Considerations should be given to official local guidance (e.g. national recommendations) regarding bacterial resistance and the appropriate use and prescription of antibacterial agents. Depending upon the resistance pattern, the following combinations can be recommended for the eradication of H. pylori:
a) Twice daily one tablet Pantoprazole
+ twice daily 1000 mg amoxicillin
+ twice daily 500 mg clarithromycin
b) Twice daily one tablet Pantoprazole
+ twice daily 400 - 500 mg metronidazole (or 500 mg tinidazole)
+ twice daily 250 - 500 mg clarithromycin
c) Twice daily one tablet Pantoprazole
+ twice daily 1000 mg amoxicillin
+ twice daily 400 - 500 mg metronidazole (or 500 mg tinidazole)
In combination therapy for eradication of H. pylori infection, the second Pantoprazole tablet should be taken 1 hour before the evening meal. The combination therapy is implemented for 7 days in general and can be prolonged for a further 7 days to a total duration of up to two weeks. If, to ensure healing of the ulcers, further treatment with pantoprazole is indicated, the dose recommendations for duodenal and gastric ulcers should be considered.
If combination therapy is not an option, e.g. if the patient has tested negative for H. pylori, the following dose guidelines apply for Pantoprazole monotherapy:
Treatment of gastric ulcer
One tablet of Pantoprazole per day. In individual cases the dose may be doubled (increase to 2 tablets of Pantoprazole daily) especially when there has been no response to other treatment. A 4-week period is usually required for the treatment of gastric ulcers. If this is not sufficient, healing will usually be achieved within a further 4 weeks.
Treatment of duodenal ulcer
One tablet of Pantoprazole per day. In individual cases the dose may be doubled (increase to 2 tablets of Pantoprazole daily) especially when there has been no response to other treatment. A duodenal ulcer generally heals within 2 weeks. If a 2-week period of treatment is not sufficient, healing will be achieved in almost all cases within a further 2 weeks.
Zollinger-Ellison-Syndrome and other pathological hypersecretory conditions
For the long-term management of Zollinger-Ellison-Syndrome and other pathological hyper secretory conditions patients should start their treatment with a daily dose of 80 mg (2 tablets of Pantoprazole 40 mg). Thereafter, the dose can be titrated up or down as needed using measurements of gastric acid secretion to guide. With doses above 80 mg daily, the dose should be divided and given twice daily. A temporary increase of the dose above 160 mg pantoprazole is possible but should not be applied longer than required for adequate acid control.
Treatment duration in Zollinger-Ellison syndrome and other pathological hyper secretory conditions is not limited and should be adapted according to clinical needs.
Patients with hepatic impairment
A daily dose of 20 mg pantoprazole (1 tablet of 20 mg pantoprazole) should not be exceeded in patients with severe liver impairment. Pantoprazole must not be used in combination treatment for eradication of H. pylori in patients with moderate to severe hepatic dysfunction since currently no data are available on the efficacy and safety of Pantoprazole in combination treatment of these patients.
Patients with renal impairment
No dose adjustment is necessary in patients with impaired renal function. Pantoprazole must not be used in combination treatment for eradication of H. pylori in patients with impaired renal function since currently no data are available on the efficacy and safety of Pantoprazole in combination treatment for these patients.
Older people
No dose adjustment is necessary in older people.
Pediatric population
Pantoprazole is not recommended for use in children below 12 years of age because of limited data on safety and efficacy in the age group.

PRECAUTIONS AND WARNINGS:
Please check the prescribing information of other drugs as well. When **Pantosel** is used in combination with those drugs.
Malignant ulcers of GI tract should be ruled out prior to use of **Pantosel** as an ulcer healing drug.
Pantosel does not cause impairment in the ability to drive and use machines.

Pregnancy:
There is no information on the excretion of pantoprazole into human breast milk.

SIDE EFFECTS:
Side effects observed include headache or diarrhoea. Rarely nausea, upper abdominal pain, flatulence, skin rash, pruritus and dizziness have been observed, in some cases edema, fever, depression and disturbances in vision (blurred vision) are reported.

Interaction with other medicaments and other forms of interactions:
Pantoprazole may reduce the absorption of drugs whose bioavailability is pH-dependent (e.g. ketoconazole).
The metabolism of Pantoprazole is in the liver via the cytochrome P450 enzyme system. Therefore an interaction of pantoprazole with other drugs or compounds which are metabolized using the same enzyme system cannot be excluded. However no clinically significant interations are observed in specific tests with a number of such drugs or compounds, namely caffeine, carbamazepine, Diazepam, Diclofenac, Digoxin, Ethanol, Glibenclamide, Metoprolol, Nifedipine, Phenytoin, Theophylline, warfarin and an oral contraceptive.
Pantosel (pantoprazole) does not interact with concomitantly administered antacids.

CONTRAINDICATIONS:
In patient with moderate to severe hepatic or renal dysfunction Pantosel must not be used as currently the data for the safety fo Pantosel in combination treatment of these patients are not available.
Pantosel should generally not be used in cases of known hypersensitivity to one of the constituents of **Pantosel** or of the combination drugs used in the treatment.

OVERDOSAGE:
There are no known symptoms of overdosage in man. In the case of overdosage with clinical signs of intoxication, the usual rules of intoxication therapy are applied.

STORAGE & INSTRUCTIONS:
Store between 15-25C.
Protect from heat, sunlight & moisture. Keep away from the reach of children.
To be sold on the prescription of a registered medical practitioner only.

HOW SUPPLIED:
Pantosel 40mg Tablet
2 x 7's Tablet.
10 x 10's Tablet.

خوراک وطریقہ استعمال:
ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:
دوا ۱۵-۲۵ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔
دھوپ، گرمی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

Manufactured by:
PHARMASOL
PRIVATE LIMITED
Plot # 549, Sundar Industrial Estate,
Lahore, Pakistan.