PUNTELA

(Pantoprazole)
40mg Tablets

پَن ٹیلا
۴۰ ملی گرام گولیاں

QUALITATIVE AND QUANTITATIVE COMPOSITION:
PUNTELA (Pantoprazole) is available for oral administration as:

PUNTELA Tablet 40mg
Each enteric coated tablet contains:
Pantoprazole as Pantoprazole Sodium Sesquihydrate USP.....40mg
(Product Specs.: USP)

CLINICAL PHARMACOLOGY:
Mechanism of Action:
Pantoprazole sodium is a proton pump inhibitor (PPI) that suppresses the final step in gastric acid production by covalently binding to the (H^+, K^+)-ATPase enzyme system at the secretory surface of the gastric parietal cell. This effect leads to inhibition of both basal and stimulated gastric acid secretion, irrespective of the stimulus. The binding to the (H^+, K^+)-ATPase results in a duration of antisecretory effect that persists longer than 24 hours for all doses tested (20mg to 120mg).

PHARMACOKINETICS:
Absorption:
Pantoprazole is rapidly absorbed and peak plasma concentrations are achieved about 2 to 2.5 hours after an oral dose. The oral bioavailability is about 77% with the enteric coated tablet formulation, and does not vary after single or multiple doses.
Administration of pantoprazole sodium delayed-release tablets with food may delay its absorption up to 2 hours or longer; however, the C_{max} and the extent of pantoprazole absorption (AUC) are not altered. Thus, **PUNTELA** delayed-release tablets may be taken without regard to timing of meals.
Distribution:
About 98% of pantoprazole sodium binds to serum protein. Volume of distribution is about 0.15 L/kg.
Metabolism:
Pantoprazole sodium is extensively metabolized in the liver through the cytochrome P450. The main metabolic pathway is demethylation by CYP2C19 with subsequent sulphate conjugation; other metabolic pathway includes oxidation by CYP3A4.
Excretion:
Terminal half-life is about 1 hour. After a single oral dose, approximately 71% of the metabolites of pantoprazole excreted in the urine, with 18% excreted in the feces through biliary secretion.
Special Population:
Children:
Following administration of single oral doses of 20 or 40 mg pantoprazole to children aged 5 - 16 years AUC and C_{max} were in the range of corresponding values in adults.

INDICATIONS:
PUNTELA (Pantoprazole) tablets is indicated in;
Children 5 years of age and above:
- Short term treatment of erosive esophagitis associated with gastroesophageal reflux disease (GERD)

Adults:
- Short term treatment of erosive esophagitis associated with gastroesophageal reflux disease (GERD)
- Gastric and duodenal ulcer
- Maintenance of Healing of Erosive Esophagitis
- Eradication of Helicobacter pylori (H. pylori) in combination with appropriate antibiotic therapy in patients with H. pylori associated ulcers
- Zollinger-Ellison-Syndrome and other pathological hyper secretory conditions

DOSAGE AND METHOD OF ADMINISTRATION:
Children 5years of age and above:

Indication	Age	Dosage	Duration
Short term treatment of erosive esophagitis associated with (GERD)	Children (5 years and older) ≥ 15kg to < 40kg	**PUNTELA** 20mg	Once daily 4 to 8 weeks
	≥ 40kg	**PUNTELA** 40mg	

Adult:

Indication	Dosage	Duration
Short term treatment of erosive esophagitis associated with (GERD)	**PUNTELA** 40mg	Once daily 4 to 8 weeks*
Gastric ulcer	**PUNTELA** 40mg	Once daily 4 to 8 weeks*
Duodenal ulcer	**PUNTELA** 40mg	Once daily 4 to 8 weeks*
Maintenance of healing of erosive esophagitis	**PUNTELA** 40mg	Once daily 4 to 8 weeks*
Eradication of H. pylori in combination with two appropriate antibiotics	**Combination 01** **PUNTELA** 40mg+1g Amoxicillin+500mg Clarithromycin	Twice daily** 1 to 2 weeks
	Combination 02 **PUNTELA** 40mg+1g Amoxicillin+400mg Metronidazole	
	Combination 03 **PUNTELA** 40mg+500mg Clarithromycin+400mg Metronidazole	
Zollinger-Ellison-Syndrome and other pathological hypersecretory conditions	**PUNTELA** 40mg	Twice daily***

Note: *In individual cases the dose may be doubled (increase to 2 tablets **PUNTELA** daily) especially when there has been no response to other treatment.
In combination therapy the second **PUNTELA tablet should be taken 1 hour before the evening meal.
***Dosage regimens should be adjusted to individual patient needs and should continue for as long as clinically indicated. Doses up to 240 mg daily have been administered (a temporary increase for adequate acid control).

Special Population:
Patients with Hepatic Impairment:
A daily dose of 20 mg pantoprazole should not be exceeded in patients with severe liver impairment.
CONTRAINDICATIONS:
PUNTELA (Pantoprazole) tablets are contraindicated in patients;
- With known hypersensitivity to any component of the formulation.

PRECAUTIONS:
Gastric Malignancy:
Symptomatic response to pantoprazole may mask the symptoms of gastric malignancy and may delay diagnosis.
Influence on Vitamin B_{12} Absorption:
In patients requiring long-term treatment, pantoprazole, as all acid-blocking medicines, may reduce the absorption of vitamin B_{12} (cyanocobalamin) due to hypo- or achlorhydria. This should be considered in patients with reduced body stores or risk factors for reduced vitamin B_{12} absorption on long-term therapy or if respective clinical symptoms are observed.
Hypomagnesaemia:
Severe hypomagnesaemia has been reported in patients treated with PPIs like pantoprazole for at least three months, and in most cases for a year. Serious manifestations of hypomagnesaemia such as fatigue, tetany, delirium, convulsions, dizziness and ventricular arrhythmia can occur but they may begin insidiously and be overlooked. In most affected patients, hypomagnesaemia improved after magnesium replacement and discontinuation of the PPI.
Tumorigenicity:
Due to the chronic nature of GERD, there may be a potential for prolonged administration of pantoprazole. In long-term studies, pantoprazole was carcinogenic and caused rare types of gastrointestinal tumors. The relevance of these findings to tumor development in humans is unknown.
Pregnancy:
PUNTELA should be used during pregnancy only if clearly needed.
Lactation:
Pantoprazole sodium excretion in human milk has been detected in a study of a single nursing mother after a single 40mg oral dose, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the benefit of the drug to the mother.

DRUG INTERACTIONS:
Medicinal products with pH-Dependent Absorption Pharmacokinetics:
Because of profound and long lasting inhibition of gastric acid secretion, pantoprazole may interfere with the absorption of other medicinal products, where gastric pH is an important determinant of oral bioavailability e.g some azole antifungals such as ketoconazole, itraconazole.
HIV Protease Inhibitors:
Concomitant use of atazanavir or nelfinavir with proton pump inhibitors is not recommended. Coadministration of atazanavir or nelfinavir with proton pump inhibitors is expected to substantially decrease atazanavir or nelfinavir plasma concentrations and may result in a loss of therapeutic effect.
Coumarin Anticoagulants (Warfarin):
There have been postmarketing reports of increased INR and prothrombin time in patients receiving **PUNTELA**, and warfarin concomitantly. Increases in INR and prothrombin time may lead to abnormal bleeding and even death. Patients treated with **PUNTELA** and warfarin concomitantly should be monitored for increases in INR and prothrombin time.

ADVERSE REACTIONS:
Common:
Headache, diarrhoea, nausea, abdominal pain, vomiting, flatulence and dizziness.
Uncommon:
Allergic reaction, pyrexia, photosensitivity reaction, facial edema, constipation, dry mouth, hepatitis, leukopenia, thrombocytopenia, elevated triglycerides, elevated liver enzyme, myalgia, arthralgia, depression, blurred vision.

OVERDOSAGE:
No specific antidote. In case of over dosage, treatment should be symptomatic and supportive.

INSTRUCTIONS:
- Store below 30°C
- Protect from light & moisture
- Keep out of reach of children

To be sold on prescription of a registered medical practitioner.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایت: دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

HOW SUPPLIED:
PUNTELA (Pantoprazole) 40mg Tablets are available in pack of 14's.

Manfactured For:
SIGMA PHARMA (International Private Limited.)
E50 North Western Industrial Zone
Port Qasim Authority, Karachi-Pakistan
www.sigmapharma.com.pk