Prada 40mg Capsule

Pantoprazole (Pellets)

پراڈا کیپسول ۴۰ ملی گرام

پینٹوپرازول (پیلٹس)

Composition:

Each Capsule contains Enteric Coated Pellets of Pantoprazole Sodium sesquihydrate (equivalent to Pantoprazole 40mg)

Pharmacological Properties:

Pharmacokinetics

The absorption of pantoprazole begins only after capsule leaves the stomach. Peak serum concentration and area under the serum concentration time curve increase in a manner proportional to doses from 10mg to 80mg. Pantoprazole does not accumulate and its pharmacokinetics are unrelated with multiple daily dosing.

Absorption:

The absorption of pantaprozole is rapid with a Cmax of 2.5µg/ml that occurs approximately 2.5 hours after single or multiple oral 40mg doses. Pantoprazole is well absorbed; it undergoes little first-pass metabolism resulting in an absolute bioavailability of approximately 77%. Pantoprazole absorption is not affected by concomitant administration of antacids. Administration of pantoprazole with food may delay its absorption up to 2 hours or longer; however the Cmax and the extent of pantoprazole absorption (AUC) are not altered. Thus, pantoprazole may be taken without regard to timing of meals.

Distribution:

The apparent volume of distribution of pantoprazole is approximately 11.0 to 23.6L, distributing mainly in extracellular fluid. The serum protein binding of pantoprazole is about 98%, primarily to albumin.

Metabolism:

Pantoprazole is extensively metabolized in the liver through the cytochrome P450 (CYP) system; pantoprazole metabolism is independent of the route of administration. The main metabolic pathway is demethylation by CYP2C19, with subsequent sulfation; other metabolic pathways include oxidation by CYP3A4. There is no evidence that any of the pantoprazole metabolites have significant pharmacological activity. Although these sub-populations of slow pantoprazole metabolizers have elimination half-life values of 3.5 to 10.0 hours, they still have minimal accumulation (≤23%) with once daily dosing.

Elimination:

After a single oral or intravenous dose of 14C-labeled pantoprazole to healthy, normal metabolizer volunteers, approximately 71% of the dose was excreted in the urine with 18% excreted in the faeces through biliary excretion. There was no renal excretion of unchanged pantoprazole.

Pharmacodynamics;

Mechanism of Action:

Pantoprazole 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.

Antisecretory Activity:

Under maximal acid stimulatory conditions using pentagastrin a dose-dependent decrease in gastric acid output occurs after a single dose of oral (20-80mg) pantoprazole in healthy volunteers. Pantoprazole once daily results in increasing inhibition of gastric acid secretion. Following the initial oral dose of 40mg pantoprazole, a 51% mean inhibition was achieved by 2.5 hours. With once a day dosing for 7 days the mean inhibition was increased to 85%. Pantoprazole suppressed acid secretion in excess of 95% in half of the subjects. Acid secretion had returned to normal within a week after the last dose of pantoprazole; there was no evidence of rebound hyper secretion. In a series of dose response studies, pantoprazole, at oral dose ranging from 20 to 120mg, caused dose-related increase in median basal gastric pH and in the percent of time gastric pH was >3 and >4. Treatment with 40mg of pantoprazole produced optimal increase in gastric pH, which was significantly greater than the 20mg dose. Doses higher than 40mg (60, 80, 120mg) did not result in further significant increase in median gastric pH.

Indications & Dosage:

Peptic ulcer (duodenal ulcer and gastric ulcer)

Moderate and severe reflux oesophagitis

For the treatment of duodenal ulcer, gastric ulcer and reflux oesophagits:

In most cases one ***Prada*** 40mg Capsule is given per day. In individual cases, the dose may be doubled (2 ***Prada*** 40mg capsules daily) especially when there has been no response to the other treatments.

Short Term Treatment of Erosive Oesophagitis

Associated with Gastro Esophageal Reflux Disease (GERD)

Prada (Pantoprazole sodium) capsules are indicated for the short-term treatment (up to 8 weeks) in the healing and symptomatic relief of erosive oesophagitis. For those patients who have not healed after 8 weeks of treatment, an additional 8 weeks course of ***Prada*** may be considered.

Maintenance of Healing of Erosive Oesophagits

Prada capsules are indicated for maintenance of healing of erosive oesophagitis and reduction in relapse rates of daytime and night time heartburn symptoms in patients with gastro esophageal reflux disease (GERD). Controlled studies did not extend beyond 12 months.

Pathological Hypersecretory Conditions Including Zollinger-Ellison syndrome

Prada capsules are indicated for the long-term treatment of pathological hypersecretory conditions including Zollinger Ellison Syndrome.

Duodenal and gastric ulcers caused by H. pylori

(Helicobacter pylori)

In Helicobacter positive patients with gastric and duodenal ulcers, a combination therapy should be applied for the eradication of the H. pylori. Depending upon the resistance pattern, the following combinations can be recommended for the eradication of H. pylori.

1. Twice daily one ***Prada*** 40mg capsule + twice daily 1000mg amoxicillin + twice daily 500mg clarithromycin
2. Twice daily one ***Prada*** 40mg capsule + twice daily 500mg metronidazole + twice daily 500mg clarithromycin
3. Twice daily one ***Prada*** 40mg capsule + twice daily 1000mg amoxicillin + twice daily 500mg metronidazole.

If combination therapy is not an option e.g if the patient has tested negative for Helicobacter pylori, ***Prada*** 40mg capsule monotheraphy is applied according to the below described dosage guidelines:

Method of usage and duration of usage

Prada 40mg capsule should not be chewed or crushed and should be swallowed whole with water 1 hour before breakfast. In combination therapy for eradication of Helicobacter pylori, the second ***Prada*** 40mg capsule should be taken before the evening meal. The combination therapy is implemented for 7 days in general and can be prolonged maximum up to two weeks. If further treatment with pantoprazole is indicated to ensure healing of the ulcers, the dosage recommendations for duodenal and gastric ulcers should be considered. A duodenal ulcer generally heals within 2 weeks. If a 2 weeks period of treatment is not sufficient, healing will be achieved in almost all cases within

a further 2 weeks. A 4-weeks period is usually required for the treatment of gastric ulcers and reflux oesophagitis. If this is not sufficient, healing will usually be achieved within further 4 weeks. As experience with long term administration in man is insufficient, treatment with ***Prada*** 40mg capsule should not exceed 8 weeks. If the drug is taken in insufficient quantity or forgotten to be taken, the delayed dose should not be taken. The therapy should be continued with the next dose according to the dose schedule of the patient. It should be consulted to a doctor about the early discontinuation or the temporary cease of the therapy.

Contraindications:

Prada capsules are contraindicated in patients with known hypersensitivity to any component of the formulation.

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

Warning / Precautions:

In the case of combination therapy, the summaries of product characteristics of the respective drugs should be observed. Prior to treatment the possibility of malignancy of gastric ulcer or a malignant disease of the esophagus should be excluded as the treatment with pantoprazole may alleviate the symptoms of malignant ulcers and can thus delay diagnosis.

To date there has been no experience with treatment in children.

There are no known effects on the ability to drive and use machines.

In case of severe liver impairment, the dose is reduced to 1 capsule (40mg pantoprazole) every other day. Furthermore, in these patients the liver enzymes should be monitored during the therapy. In case of a rise of the liver enzymes, ***Prada*** 40mg capsule should be discontinued. The daily dose of 40mg pantoprazole should not be exceeded in elderly patients or in those with impaired renal function. An exception is combination therapy for eradication of H. pylori, where also elderly patients should receive the usual pantoprazole dose (2 x 40mg / day) during 1-week treatment.

Side effects / Adverse effects:

Treatment with ***Prada*** 40mg capsule can occasionally lead to headache or diarrhoea.

There have been rare reports of nausea, upper abdominal pain, flatulence, skin rash and dizziness.

Edema, fever, the onset of depression or blurred vision was reported in individual cases.

Interaction with other medicaments and other Forms of Interactions:

Prada 40mg capsule may reduce the absorption of drugs whose bioavailability is pH-dependent (e.g Ketoconazole).

Pantoprazole is metabolized in the liver via the cytochrome P450 enzyme system. An interaction of pantoprazole with other drugs or compounds which are metabolized via the same enzyme system, cannot be excluded. No clinically significant interaction were, however, observed in specific tests with carbamazepine, caffeine, diazepam, diclofenac, digoxin, ethanol, glibenclamide, metoprolol, nifedipine, phenprocoumon, phenytion, theophyline, warfarin and an oral contraceptive.

There were no interactions with concomitantly administered antacids.

No clinically relevant interactions were observed with clarithromycin, metronidazole and amoxicillin

Overdose and Treatment:

When intoxication symptoms are observed due to the overdose, the symptomatic and supportive treatment is applied.

Storage Conditions:

Store at temperature below 25˚C

Presentation and Packaging quantity:

Alu Alu pack 1x14's where each capsule contains 40mg pantoprazole.

پـــراڈا کیپسول ۴۰ ملی گرام

پینٹوپرازول (پیلٹس)

پیشکش: **پـــراڈا** کیپسول میں پینٹوپرازول ۴۰ ملی گرام ہے۔

خوراک اور طریقہ استعمال: پراڈا کیپسول میں ۴۰ ملی گرام پینٹوپرازول موجود ہے جو معدہ کی تیزابی رطوبت کو روکتا ہے۔

پـــراڈا کیپسول کی خوراک کا تعین مریض کی کیفیت کے حساب سے کیا جاتا ہے۔ بہترین نتائج کے لئے معالج کی ہدایت پر عمل کریں۔

پـــراڈا کیپسول درج ذیل تکالیف میں دیا جاسکتا ہے۔

۱۔	آنتوں کا السر	ایک کیپسول روزانہ آٹھ ہفتہ تک
۲۔	معدہ کا السر	ایک کیپسول روزانہ آٹھ ہفتہ تک
۳۔	زلنگر ایلسن سنڈروم	ایک کیپسول روزانہ آٹھ ہفتہ تک
۴۔	زولنگر ایلسن سنڈروم	پراڈا کیپسول زولنگر ایلسن سنڈروم میں لمبے عرصے تک دینا چاہئے۔

ممنوعات و احتیاط: دوا ہمیشہ معالج کے مشورہ سے اور ہدایات کے مطابق استعمال کریں۔ اس دوا کے استعمال سے کوئی اور اثر مثلاً متلی، سر درد، مروڑ، قبض اور گیس وغیرہ ہونے کے امکانات بہت کم ہیں۔ بچوں، حاملہ اور دودھ پلانے والی خواتین میں دوا کا استعمال ممنوع ہے۔

روشنی سے محفوظ ۲۵ ڈگری سینٹی گریڈ سے کم درجہ حرارت میں رکھیں۔ تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

Manufactured by:
SHAROOQ PHARMACEUTICALS (PVT) LTD.
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Marketed by:
CENRJY Pharmaceuticals