P-lock
Pantoprazole

Composition
P-lock 20 tablet: Each delayed release tablet contains Pantoprazole Sodium Sesquihydrate USP equivalent to Pantoprazole 20 mg.
P-lock 40 tablet: Each delayed release tablet contains Pantoprazole Sodium Sesquihydrate USP equivalent to Pantoprazole 40 mg.

Pharmacology
Pantoprazole (P-lock) is chemically a novel substituted benzimidazole derivative, which suppresses the final step in gastric acid production by forming a covalent bond to two sites of the H^+, K^+ - ATPase enzyme system at the secretory surface of the gastric parietal cell. This leads to inhibition of both basal and stimulated gastric acid secretion irrespective of the stimulus. The binding to the H^+/K^+ - ATPase results in duration of antisecretory effect that persists longer than 24 hours. Pantoprazole (P-lock) is quantitatively absorbed and bioavailability does not change upon multiple dosing. Pantoprazole (P-lock) is extensively metabolized in the liver. Almost 80% of an oral dose is excreted as metabolites in urine; the remainder is found in feces and originates from biliary secretion.

Indication
Pantoprazole (P-lock) is indicated where suppression of acid secretion is of therapeutic benefit. Pantoprazole (P-lock) is registered for the following indications: -
1. Peptic ulcer diseases (PUD)
2. Gastro esophageal reflux diseases (GERD)
3. Treatment of ulcer resistant to H_2 receptor antagonists (H_2RAs)
4. Treatment of ulcers induced by non-steroidal anti-inflammatory drugs (NSAIDs)
5. Gastrointestinal (GI) bleeding from stress or acid peptic diseases
6. Eradication of *Helicobacter pylori* (in combination with antibiotics)
7. Zollinger-Ellison syndrome
8. Prophylaxis for acid aspiration syndrome during induction of anaesthesia

Dose and Administration
Route of administration: Oral
Delayed release tablet: The usual recommended adult oral dose is 40 mg given once daily, before breakfast. The duration of therapy is ranging from 2-8 weeks. *Duodenal Ulcers:* P-lock 40 mg tablet, once daily for 2 to 4 weeks. Duodenal ulcer generally heals within 2 weeks. *Gastric ulcers:* P-lock 40 mg tablet, once daily for 4 to 8 weeks. Gastric ulcer generally heals within 4 weeks. *Reflux esophagitis:* P-lock 40 mg tablet, once daily for 4 to 8 weeks. Reflux esophagitis generally heals within 4 weeks of treatment. *In resistant ulcers:* P-lock 40 mg tablet, once daily for 8 weeks. *Ulcers induced by NSAIDs:* P-lock 40 mg tablet once daily, in patients receiving continuous treatment with NSAIDs. *GI bleeding from stress or acid peptic diseases:* Usual adult oral dosage, if required the dosage may be increased. *Eradication of Helicobacter pylori:* Triple therapy of P-lock 40 mg twice daily in combination with appropriate antibiotic for one week achieved eradication rates of 90 to100%. *Zollinger-Ellison syndrome:* 4 P-lock 40 mg tablets per day. Once control of acid secretion has been achieved, the dose should be gradually reduced to the lowest effective dose that maintains acid control. *Prophylaxis for acid aspiration syndrome during induction of anaesthesia:* 1 or 2 P-lock 40 mg tablet should be given the evening before surgery and repeated again the morning of surgery.
Maintenance therapy: Maintenance treatment should involve the lowest dose of the drug. Both 20 and 40 mg doses of Pantoprazole (P-lock) are safe and effective in maintaining patients with healed reflux esophagitis and PUD in remission.

Contraindication
P-lock delayed release tablets are contraindicated in patients with known hypersensitivity to any of the formulation.

Warning & Precaution
Patients should be cautioned that P-lock delayed release tablets should not be split, chewed or crushed.

Side effects
Common: Potentially life-threatening effects: None has been reported with respect to Pantoprazole.
Severe or irreversible adverse effects: No serious adverse reactions have been described to date.
Symptomatic adverse effects: Headache (1.3%) and diarrhoea (1.5%) are the two commonest reported adverse events. It doesn't influence renal, cardiovascular, respiratory, endocrine, cognitive or motor functions and no consistent change have been found in any biochemical or haematological parameters.
Rare: Peripheral edema has occasionally been reported in female patients. Other side effects may include abdominal pain, dizziness, nausea, epigastric discomfort, flatulence, skin rash, pruritus etc.

Use in Pregnancy & Lactation
Pregnant women: USFDA pregnancy category B. Studies using animals have not found any risk to the fetus.
Lactating mother: There are no data on the excretion of Pantoprazole into the breast milk.

Use in Children & Adolescents
No adequate data are available.

Elder patient
No problems with Pantoprazole have been encountered in clinical use in this patient group.

Concurrent disease
No dosage adjustment of Pantoprazole is required in patients with mild, moderate or severe renal insufficiency or in elderly patients. No dosage adjustment is necessary in patients undergoing haemodialysis. No dosage adjustment is needed in patients with mild or moderate hepatic impairment. In hepatic cirrhosis, it is recommended that the dosing is reduced to every other day.

Drug Interactions
With Medicine: Pantoprazole is metabolized through the cytochrome P-450 system, and subsequently undergoes Phase II conjugation. Based on studies evaluating possible interactions of Pantoprazole with other drugs metabolized by the cytochoreme P-450 system, no dosage adjustment is needed with concomitant use of the following drugs; theophylline, antipyrine, caffeine, carbamazepine, diazepam, diclofenac, digoxin, ethanol, glyburide, an oral contraceptive (Levonorgestrel/ethinyl estradiol), metoprolol, nifedipine, phenytion, or warfarin. There was also no interaction with concomitantly administered antacids.
With food & others: No significant interactions have been observed in clinical studies.

Overdosage
There are no known symptoms of overdosage in humans. Since Pantoprazole is highly protein bound, it is not readily dialyzable. Apart from symptomatic and supportive management, no specific therapy is recommended.

Storage
Store below 30° C temperature and cool and dry place, away from light. Keep out of the reach of children.

Packing
P-lock 20 tablet: Each box contains 6 Alu-Alu blister of 10 tablets.
P-lock 40 tablet: Each box contains 3 Alu-Alu blister of 10 tablets.

Manufactured by
ONE PHARMA LTD.
C-23-24, BSCIC I/A
Bogura, Bangladesh
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