Alton
Esomeprazole

Presentation

Alton 20: Each enteric-coated tablet contains Esomeprazole 20 mg (as Esomeprazole Magnesium Trihydrate USP).

Alton 40: Each enteric-coated tablet contains Esomeprazole 40 mg (as Esomeprazole Magnesium Trihydrate USP).

Alton 40 IV Injection: Each vial contains Esomeprazole INN 40 mg (as lyophilized powder of Esomeprazole Sodium) and each ampoule contains 5 ml of 0.9% Sodium Chloride BP Injection.

Pharmacodynamics
Esomeprazole is the S-isomer of Omeprazole. It acts as a proton pump inhibitor that suppresses gastric acid secretion by specific inhibition of the H+/K+-ATPase in the gastric parietal cell. By acting specifically on the proton pump, Esomeprazole blocks the final step of acid production, thus reducing gastric acidity.

Pharmacokinetics

Absorption
Bioavailability is approximately 90% (repeated once daily dosing) and 64% (single dose).

Distribution
Esomeprazole is 97% bound to plasma proteins. The apparent volume of distribution at steady state in healthy volunteers is approximately 16 L.

Metabolism
Esomeprazole is extensively metabolized in the liver by the cytochrome P450 (CYP) enzyme system.

Excretion
Esomeprazole is excreted as metabolites primarily in urine but also in feces. Less than 1% of parent drug is excreted in the urine.

Indications
Alton is indicated for-

- Risk Reduction of NSAID-associated gastric ulcer & duodenal ulcer
- Treatment of gastro esophageal reflux disease (GERD)
- Healing of erosive esophagitis
- Peptic ulcer diseases (PUD)
- *H. pylori* eradication (Triple therapy)
- Zollinger-Ellison syndrome

Dosage and Administration

Tablet

Indications	Dose and Frequency
Healing of erosive esophagitis	20 mg or 40 mg once daily
Symptomatic GERD	20 mg once daily
Risk reduction of NSAID associated gastric ulcer	20 mg or 40 mg once daily
Duodenal ulcer associated *H. Pylori* eradication (in combination with antibiotics)	20 mg twice daily

Injection

Duodenal ulcer, Gastric ulcer, Gastrointestinal lesions refractory to H_2 blockers, Zollinger-Ellison syndrome	40 mg per day intravenously
Severe peptic ulcer bleeding	80 mg over 30 minutes initially by IV infusion, then by continuous infusion 8 mg/hour for 72 hours, then by mouth 40 mg per day.
NSAIDs associated gastric ulcer, Gastro esophageal reflux disease (GERD) with erosive esophagitis	20-40 mg per day intravenously

Direction for use of IV injection
Esomeprazole lyophilized powder and 0.9% Sodium Chloride Injection is for intravenous administration only and must not be given by any other route. Esomeprazole injection 40 mg should be given as a slow intravenous injection. The solution for IV injection is obtained by adding 5 ml 0.9% Sodium Chloride Injection to the vial containing powder. After reconstitution the injection should be given slowly over a period of at least 3 minutes. Use only freshly prepared solution. The reconstituted solution may be stored at room temperature (up to 30◦c) for a maximum 12 hours. Half of the IV injection should be used when 20 mg to be administered.

Direction for use of IV infusion
Esomeprazole IV 40 mg should be given as an intravenous infusion over a period of 10 to 30 minutes. Esomeprazole IV should be reconstituted with 5 ml of 0.9% Sodium Chloride Injection and further diluted (admixed) with 5% Dextrose Injection or 0.9% Sodium Chloride Injection or Lactated Ringer's Injection to a final volume of 50 ml. The reconstituted solution may be stored at room temperature (up to 30◦c) for a maximum 12 hours prior to dilution. The admixed solution may be stored at room temperature (up to 30◦c) and must be used within 12 hours when reconstituted with 0.9% Sodium Chloride Injection or Lactated Ringer's Injection and within 6 hours when reconstituted with 5% Dextrose Injection.

Contraindication
Esomeprazole is contraindicated in those who have known hypersensitivity to any other components of the formulation or to substituted benzimidazoles.

Side effects
In general, Esomeprazole is well tolerated in both short and long-term use. Common side effects reported with Esomeprazole include headache, diarrhea, abdominal pain, flatulence, nausea and constipation.

Precautions
Proton pump inhibitors may mask the symptoms of gastric cancer; particular care is required in those presenting with 'alarm features' (bleeding, recurrent vomiting, dysphagia), in such cases gastric malignancy should be ruled out before treatment.

Drug interactions
Esomeprazole inhibits gastric acid secretion and may interfere with the absorption of drugs where gastric pH is an important determinant of bioavailability. Patients treated with Esomeprazole and Warfarin concomitantly may need to be monitored. Esomeprazole reduces the antiplatelet activity of Clopdogrel.

Use in pregnancy & lactation
There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed. Esomeprazole is likely to be excreted in human milk; a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Storage conditions
Store in a cool (below 30◦ c) and dry place. Protect from light and keep out of reach of children. Store in carton until time of use.

Commercial pack

Alton 20: Each box contains 3 blister packs of 10 tablets.

Alton 40: Each box contains 3 blister packs of 10 tablets.

Alton 40 IV injection: Each box contains one vial of lyophilized powder of Esomeprazole 40 mg, one ampoule of 5 ml 0.9% Sodium Chloride Injection and one sterile disposable syringe (5 ml).

Manufactured by :
general GENERAL Pharmaceuticals Ltd.
Gazipur, Bangladesh

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