Esoprol

Esomeprazole

Composition
Esoprol 20 Capsule: Each capsule contains 20 mg of Esomeprazole as enteric coated pellets of Esomeprazole Magnesium Trihydrate USP.
Esoprol 40 Capsule: Each capsule contains 40 mg of Esomeprazole as enteric coated pellets of Esomeprazole Magnesium Trihydrate USP.
Esoprol 40 IV Injection: Each vial contains Esomeprazole 40 mg (as lyophilized powder of Esomeprazole Sodium BP)

Description
Esomeprazole is a proton pump inhibitor that suppresses gastric acid secretion by specific inhibition of the H^+/K^+-ATPase in the gastric parietal cell. The S-and R-isomers are protonated and converted in the acidic compartment of the parietal cell forming the active inhibitor. By acting specifically on the proton pump, esomeprazole blocks the final step in acid production, thus reducing gastric acidity.

Indications
It is indicated for the treatment of Gastro-Esophageal Reflux Disease (GERD), healing of Erosive Esophagitis, maintenance of healing of Erosive Esophagitis, symptomatic Gastro-Esophageal Reflux Disease, *H.pylori* eradication to reduce the risk of Duodenal Ulcer recurrence, Zollinger-Ellison Syndrome, Acid related Dyspepsia, Duodenal and Gastric Ulcer also reduce the risk of NSAID associated Gastric Ulcer.

Dosage & Administration
Esoprol capsules should be adminstrated one hour before meal, swallowed whole and should not be crushed or chewed.

Adult Dose

Indication	Dose	Frequency
Gastroesophageal reflux disease (GERD)	20 mg or 40 mg	Once daily for 4 to 8 weeks
Healing of erosive esophagitis	20 mg	Once daily
Maintenance of healing of erosive esophagitis	20 mg	Once daily
Symptomatic gastro-esophageal reflux	20 mg	Once daily for 4 weeks
Risk reduction of NSAID-associated gastric ulcer	20 mg or 40 mg	Once daily for 6 months
H. pylori eradication to reduce the risk of duodenal ulcer recurrence	20 mg	Twice daily for 10 days
Triple therapy:		
Esomeprazole	20 mg	Twice daily for 10 days
Amoxycillin	1000 mg	Twice daily for 10 days
Clarithromycin	500 mg	Twice daily for 10 days
Pathological hypersecretory conditions including Zollinger-Ellison syndrome	40 mg	Twice daily or more

Paediatric Dose: (1-12 years old)

Indication	Dose	Frequency
Symptomatic gastro-esophageal reflux: weight > 10 kg	10 mg	Once daily for up to 8 weeks
GERD:		
weight 10-20 kg weight > 20 kg	10 mg 10 mg -20 mg	Once daily for 8 weeks

*The majority of patients are healed within 4 to 8 weeks. For patients who do not heal after 4-8 weeks, an additional 4-8 weeks treatment may be considered.

Esoprol 40 IV Injection: Duodenal ulcer, gastrointestinal lesions refractory to H_2 blockers, Zollinger-Ellison syndrome: 40 mg per day intravenously, Reflux Esophagitis:20-40 mg per day intravenously.

Directions for reconstitution of solution for injection
Add 5 ml sterile solution of (Sodium Chloride BP 0.9% w/ v) with one vial of Esomeprazole to make injectable solution. Administer intravenously over a period of at least 3 minutes. For 20 mg, half of the IV solution should be used. Administer the mixed solution within 12 hours.

Contraindications
Esomeprazole is contraindicated in those patients who have known hypersensitivity to any component of the formulation.

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

Precautions
Exclude the possibility of malignancy when gastric ulcer is suspected and before treatment of dyspepsia.
Geriatric: Dosage adjustment is not necessary.
Renal insufficiency: Dosage adjustment is not necessary.
Hepatic insufficiency: Dosage adjustment is not necessary in patients with mild to moderate liver impairment. However, in patients with severe hepatic insufficiency, a dose of 20 mg once daily of Esomeprazole should not be exceeded.

Use in pregnancy & lactation
Pregnancy Category C
Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well - controlled studies in human, but potential benefits may warrant use of the drug in pregnant women despite potential risks. Esomeprazole is likely to be excreted in milk; decision should be made whether to discontinue nursing or to discontinue to the drug, taking into account the importance of the drug to the mother.

Drug Interactions
Concomitant use of Atazanavir and Nelfinavir with Esomeprazole is not recommended. Co-administration of Saquinavir, digoxin and Tacrolimus with Esomeprazole is expected to increase the concentration of Saquinavir,Digoxin and Tacrolimus respectively. Co-administration of Diazepam and Methotrexate with Esomeprazole result in a 45% decreases in clearance of Diazepam and may elevate and prolongs serum level of Methotrexate.
Clopidogrel is metabolized to its active metabolite in part by CYP2C19. Concomitant use of Esomeprazole results in reduced plasma concentration of the active metabolite of Clopidogrel and a reduction in platelet inhibition.

Overdosage
There is no experience to data with deliberate overdose. Data are limited but single dose of 80 mg of Esomeprazole were uneventful. Esomeprazole is extensively plasma protein bound and is therefore not readily dialysable. As in any case of overdose, treatment should be symptomatic and general supportive measures should be utilized.

Storage
Do not store above 30° C. Keep in a dry place and protect from light. Keep out of reach of children.

Packaging
Esoprol 20 Capsule: Each carton contains 6 x 10's capsules in blister pack.
Esoprol 40 Capsule: Each carton contains 4 x 8's capsules in blister pack.
Esoprol 40 IV injection: Each box contains one vial of Esomeprazole 40 mg (as lyophilized powder of Esomeprazole Sodium BP), one ampoule of 5 ml sterile solution of (Sodium Chloride BP 0.9% w/ v) & one 5 ml sterile disposable syringe.

Manufactured by
ZISKA PHARMA
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Kaliakoir, Gazipur, Bangladesh

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