

Composition : Esomeprazole 20mg & 40mg Tablet/Capsule & 40mg (IV) Injection.

Indications and uses :

- 1) Treatment of Gastroesophageal Reflux Disease (GERD)
- 2) H. Pylori eradication to reduce the risk of duodenal ulcer recurrence.

Dosage & administration :

Recommended adult dosage schedule of Pronex :

Indication	Dose	Frequency
Gastroesophageal Reflux Disease		
Healing of erosive esophagitis.	20/40mg	Once daily for 4-8 weeks
Maintenance of healing of erosive esophagitis.	20mg	Once daily
Symptomatic gastroesophageal reflux disease.	20mg	Once daily for 4 weeks
H. Pylori eradication to reduce the risk of duodenal ulcer recurrence		
Pronex (Esomeprazole)	40mg	Once daily for 10 days
Amoxicillin	1000mg	Twice daily for 10 days
Clarithromycin	500mg	Twice daily for 10 days
Dosage for Children (12 to 17 years):		
Short term treatment of GERD	20/40mg	Once daily up to 8 weeks.

The recommended adult dose is either 20 or 40mg Esomeprazole given once daily by intravenous injection (no less than 3 minutes) or intravenous infusion (10 to 30 minutes).

Or, as directed by the registered physician.

Direction for use of IV injection : The Esomeprazole powder should be reconstituted with 5ml or 0.9% Sodium Chloride Injection, USP. The reconstituted solution should be administered as an intravenous injection over no less than 3 minutes. The reconstituted solution should be stored at room temperature up to 30°C (86°F) and administered within 12 hours after reconstitution. No refrigeration is required.

Direction for use of IV infusion : A solution for intravenous infusion is prepared by first reconstituting the contents of one vial with 5ml of 0.9% Sodium Chloride Injection, USP, Lactated Ringer's Injection, USP or 5% Dextrose Injection, USP and further diluting the resulting solution to a final volume of 50ml. The solution should be administered as an intravenous infusion over a period of 10 to 30 minutes. The admixture solution

Pronex
Tablet / Capsule / Inj.

should be stored at room temperature up to 30°C and should be administered within 12 hours when

reconstituted with 0.9% Sodium Chloride Injection or Lactated Ringer's Injection and 6 hours when reconstituted with 5% Dextrose injection. Or, as directed by the registered physician.

Contraindication : Esomeprazole is contraindicated in patients with known hypersensitivity to any component of the formulation.

Side effects : Adverse effects resemble those of other proton-pump inhibitors and include headache, nausea, vomiting, diarrhea, and abdominal pain.

Drug interactions : Interaction with other drugs, no report so far has been reported.

Use in pregnancy and lactation : Pregnancy category B by the FDA.

Packing :

Pronex-20 : 5 x 10's capsules in blister pack.

Pronex-40 : 4 x 7's capsules in blister pack.

Pronex-20 : 4 x 14's tablets in blister pack.

Pronex-40 : 4 x 14's tablets in blister pack.

Pronex-40 Injection : Combipack.