

Composition

Nexe 20 Tablet: Each enteric coated tablet contains 20 mg of Esomeprazole as Esomeprazole Magnesium Trihydrate BP.

Nexe 40 Tablet: Each enteric coated tablet contains 40 mg of Esomeprazole as Esomeprazole Magnesium Trihydrate BP.

Nexe 20 Capsule: Each capsule contains enteric coated pellets of Esomeprazole Magnesium Trihydrate BP 22.2 mg equivalent to Esomeprazole 20 mg.

Nexe 40 Capsule: Each capsule contains enteric coated pellets of Esomeprazole Magnesium Trihydrate BP 44.4 mg equivalent to Esomeprazole 40 mg.

Nexe 40 IV Injection: Each vial contains sterile lyophilized powder of Esomeprazole Sodium INN equivalent to Esomeprazole 40 mg.

Pharmacology

Esomeprazole (**Nexe**) is 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, Nexe blocks the final step in acid production, thus reducing gastric acidity.

Indication

Treatment of Gastroesophageal Reflux Disease (GERD), Healing of Erosive Esophagitis, Maintenance of Healing of Erosive Esophagitis, Symptomatic Gastroesophageal Reflux Disease, H. pylori eradication to reduce the risk of Duodenal Ulcer recurrence, Zollinger-Ellison Syndrome, Acid Related Dyspepsia, Duodenal and Gastric Ulcer

Dosage & Administration

Tablet/Capsule/Suspension: The recommended adult dosages are outlined in the table below. Nexe delayed release tablet/capsule/suspension should be swallowed whole and taken at least one hour before eating.

Recommended Dosage Schedule:

Indication	Dose	Frequency
Gastroesophageal Reflux Disease (GERD) Healing of Erosive Esophagitis	20 mg or 40 mg	Once Daily for 4 to 8 Weeks*
Maintenance of Healing of Erosive Esophagitis	20 mg	Once Daily
Symptomatic Gastroesophageal Reflux Disease	20 mg	Once Daily for 4 Weeks**
Pediatric GERD		
12 to 17 Year Olds: Short-term Treatment of GERD	20 mg or 40 mg	Once Daily for up to 8 Weeks
1 to 11 Year Olds*: Short-term Treatment of Symptomatic GERD	10 mg	Once Daily for up to 8 Weeks
Healing of Erosive Esophagitis		
weight <20 kg	10 mg	Once Daily for 8 Weeks
weight ≥20 kg	10 mg or 20 mg	Once Daily for 8 Weeks
Risk Reduction of NSAID-Associated Gastric Ulcer	20 mg or 40 mg	Once Daily for up to 6 months
H. pylori eradication to reduce the risk of Duodenal Ulcer recurrence		
Triple Therapy:		
Esomeprazole	40 mg	Once Daily for 10 Days
Amoxicillin	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

*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 of treatment may be considered.

**If symptoms do not resolve completely after 4 weeks, an additional 4 weeks of treatment may be considered.

Injection

GERD with Erosive Esophagitis:

Adults: Dose is either 20 mg or 40 mg Esomeprazole given once daily by intravenous injection (not less than 3 minutes) or intravenous infusion (10 minutes to 30 minutes).

Pediatric: Give the following doses once daily as an intravenous infusion over 10 minutes to 30 minutes.

1 year to 17 years:

Body weight less than 55 kg: 10 mg

Body weight 55 kg or greater: 20 mg

1 month to less than 1 year of age: 0.5 mg/kg

Directions for reconstitution of solution

Solution for injection is prepared by adding 5 ml of 0.9% Sodium Chloride for intravenous injection into the vial containing the dry powder. The reconstituted solution for injection is clear and colorless to very slightly yellow.

Administration

IV injection must be administered intravenously over a period of at least 3 minutes. Prepared solution must be used within 12 hours of preparation and can be exposed to normal indoor lighting at a maximum of 30° C.

Geriatric: No dosage adjustment is necessary. **Renal Insufficiency:** No dosage adjustment is necessary. **Hepatic Insufficiency:** No dosage adjustment is necessary in patients with mild to moderate liver impairment. For patients with severe liver impairment, a dose of 20 mg of Nexe should not be exceeded.

Contraindication

Esomeprazole is contraindicated in patients with known hypersensitivity to any component of the formulation or to substituted Benzimidazoles.

Precaution

Symptomatic response to therapy with Esomeprazole does not preclude the presence of gastric malignancy. Atrophic gastritis has been noted occasionally in gastric corpus biopsies from patients treated long-term with omeprazole, of which Esomeprazole is an enantiomer.

Side Effects

In general, Esomeprazole was well tolerated in both short- and long-term clinical trials. The most frequently occurring adverse events (>1%) are headache and diarrhea. nausea, flatulence, abdominal pain, constipation and dry mouth occurred at similar rates among patients taking Esomeprazole.

Use in Pregnancy and Lactation

In Pregnancy: Pregnancy Category C. This drug should be used during pregnancy only if clearly needed.

In Lactation: The excretion of Esomeprazole in milk has not been studied. As 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.

Drug Interaction

Drug interaction studies have shown that Esomeprazole does not have any clinically significant interactions with Phenytoin, Warfarin, Quinidine, Clarithromycin or Amoxicillin. Esomeprazole inhibits gastric acid secretion. Therefore, Esomeprazole may interfere with the absorption of drugs where gastric pH is an important determinant of bioavailability (eg, Ketoconazole, Iron salts and Digoxin). Coadministration of oral contraceptives, Diazepam, Phenytoin or Quinidine did not seem to change the pharmacokinetic profile of Esomeprazole.

Overdose

Esomeprazole overdose can lead to drowsiness, vision problems, nausea, sweating, flushing, headache, dry mouth, rapid heartbeat.

Storage

Keep away from light & moisture and store below 30° C. Keep out of the reach of children.

Packaging

Nexe 20 Tablet: Each Box contains 6X10's tablets in Alu-Alu blister pack.

Nexe 40 Tablet: Each Box contains 3X10's tablets in Alu-Alu blister pack.

Nexe 20 Capsule: Each Box contains 6X10's capsules in Alu-Alu blister pack.

Nexe 40 Capsule: Each Box contains 6X10's capsules in Alu-Alu blister pack.

Nexe 40 IV Injection: Each box contains 1 vial of lyophilized Esomeprazole 40 mg, 1 ampoule of 5 ml 0.9% Sodium Chloride BP injection for intravenous injection and 1 sterile syringe (5 ml).