

# NEXE Esomeprazole

20 mg Tablet

## DESCRIPTION

NEXE (Esomeprazole) is an antiulcerant drug belongs to proton pump inhibitor (PPI) class. Esomeprazole is the therapeutically active isomer (S-isomer) of Omeprazole. Esomeprazole blocks the final step of acid production by specific inhibition of the H<sup>+</sup>/K<sup>+</sup> ATPase enzyme system (proton pump) at the secretory surface of the gastric parietal cell. This effect is dose-related and inhibits both basal and stimulated acid secretion regardless of the stimulus.

## COMPOSITION

NEXE Tablet : Each tablet contains Esomeprazole Magnesium INN equivalent to 20 mg Esomeprazole.

## INDICATION

NEXE (Esomeprazole) is indicated for the treatment or symptomatic relief of various gastric disorders including

- Gastric and duodenal ulcers
- NSAID-induced duodenal or gastric ulcers and gastroduodenal erosions
- Prophylaxis of NSAID-induced gastroduodenal complications in patients who require continued NSAID treatment
- Gastroduodenal ulcer associated with *Helicobacter pylori* in combination with antibiotics
- Gastro-oesophageal reflux disease (GERD)/Reflux oesophagitis, erosive oesophagitis
- Acid-related dyspepsia
- Zollinger-Ellison Syndrome

## DOSAGE AND ADMINISTRATION

Dosage should be individualized, depending on patient's condition and response.

NEXE (Esomeprazole) should be taken before meal.

Gastric ulcers	20-40 mg once daily for 4-8 weeks	
GERD	Treatment dose	40 mg once daily for 4 weeks, continued for further 4 weeks if not fully healed or symptoms persist
	Maintenance dose	20 mg daily
Symptomatic treatment in the absence of oesophagitis		20 mg daily for up to 4 weeks, then 20 mg daily when required
NSAID-induced ulcers	20 mg once daily for 4-8 weeks	
Prophylaxis of NSAID-induced gastroduodenal complications	20 mg daily	
Acid-related dyspepsia	20-40 mg once daily for 2-4 weeks according to response	
Zollinger-Ellison syndrome	20-80 mg once daily, the dose should be adjusted individually and treatment continued as long as clinically indicated	
Eradication of <i>Helicobacter pylori</i>	20 mg Esomeprazole twice daily + Amoxicillin 1000 mg twice daily / Metronidazole 400 mg twice daily + 500 mg Clarithromycin	

**Renal impairment** : Dose adjustment is not required. **Hepatic impairment** : No dosage adjustment is necessary in mild to moderate hepatic impairment but in severe hepatic impairment the maximum daily dose of Esomeprazole is 20 mg.

## CONTRAINDICATION

NEXE is contraindicated in known hypersensitivity to Esomeprazole.

## PRECAUTION

Esomeprazole should be used with caution in liver disease and in gastric malignancy because Esomeprazole may mask the symptoms of gastric cancer.

## IN PREGNANCY AND LACTATION

**Pregnancy** : Pregnancy category B. Use during pregnancy only if the potential benefit justifies the possible risk of the fetus. **Lactation** : It is not known whether Esomeprazole is secreted in breast-milk. It should be used with caution in nursing mothers and only if the expected benefit to the mother is greater than the possible risk to the nursing infant.

## SIDE EFFECT

Esomeprazole is generally well tolerated. Nausea, headache, diarrhea, constipation, flatulence, skin rash have been reported but are rare and usually mild and transient.

## DRUG INTERACTION

**Valdecoxib** : Plasma concentration of Esomeprazole is increased. **Clarithromycin** : Plasma concentration of both drugs are increased. **Drugs that absorption are depends on gastric pH like, Itraconazole, Ketoconazole, Ampicillin, Iron salts, Cyanocobalamin** : Esomeprazole reduces their absorption due to its profound inhibition of gastric acid secretion. **Coumarin, Phenytoin, Diazepam, Digoxin, Tacrolimus, Cilostazol, Methotrexate** : Esomeprazole possibly increases their plasma concentration.

## STORAGE

Store in a cool dry place, away from light. Keep out of reach of children.

## HOW SUPPLIED

NEXE Tablet : Box containing 3 x 10's tablet in Alu-Alu strips.



Manufactured by  
**Apex Pharma Ltd.**  
Shafipur, Gazipur