

Esomeprazole

COMPOSITION

Maxima® 20 Tablet: Each enteric coated tablet contains Esomeprazole magnesium Trihydrate BP equivalent to Esomeprazole 20 mg

Maxima® 40 Tablet: Each enteric coated tablet contains Esomeprazole magnesium Trihydrate BP equivalent to Esomeprazole 40 mg

Maxima® 20 Capsule: Each capsule contains Esomeprazole magnesium Trihydrate BP equivalent to Esomeprazole 20 mg as enteric coated pellets.

Maxima® 40 Capsule: Each capsule contains Esomeprazole magnesium Trihydrate BP equivalent to Esomeprazole 40 mg as enteric coated pellets.

Maxima® IV Injection: Each Vial Contains lyophilized powder of Esomeprazole Sodium INN equivalent to Esomeprazole 40 mg.

Maxima® MUPS 20 Tablet: Each MUPS (Multiple-Unit Pellet System) tablet contains 20 mg Esomeprazole (as Esomeprazole Magnesium Trihydrate USP enteric coated pellets).

Maxima® MUPS 40 Tablet: Each MUPS (Multiple-Unit Pellet System) tablet contains 40 mg Esomeprazole (as Esomeprazole Magnesium Trihydrate USP enteric coated pellets).

PHARMACOLOGY

Esomeprazole is a proton pump inhibitor that suppresses gastric acid secretion by inhibition of the H⁺/K⁺ -ATPase in the gastric parietal cell thus reducing gastric acidity. After oral administration, peak plasma levels (C_{max}) occur at approximately 1.5 hours (T_{max}). Esomeprazole is 97% bound to plasma proteins. Esomeprazole is metabolized in the liver by the cytochrome P450 enzyme system. Approximately 80% of an oral dose of Esomeprazole is excreted as inactive metabolites in the urine and the remainder is found as inactive metabolites in the feces.

INDICATIONS

1. Healing of Erosive Esophagitis
2. Maintenance of healing of Erosive Esophagitis
3. Gastroesophageal Reflux Disease (GERD)
4. NSAID-associated gastric ulcer
5. H. pylori eradication (Triple Therapy)
6. Zollinger-Ellison syndrome

DOSAGE AND ADMINISTRATION

Tablet/Capsule/MUPS Tablet:

Adult (from age of 18):

Indication	Dose	Frequency
Gastroesophageal Reflux Disease (GERD)		
Erosive esophagitis	40 mg	Once daily for 4 weeks
Maintenance therapy of healing of erosive esophagitis	20 mg	Once daily
NSAID-associated gastric ulcer	20 mg	Once daily for 4 to 8 weeks
H. pylori eradication (Esomeprazole MUPS tablet with Amoxicillin and Clarithromycin)	20 mg	Twice daily for 7 days
Zollinger-Ellison syndrome	40 mg to 80 mg	Twice daily

Children (12 to 17 years old):

Indication	Dose	Frequency
Gastroesophageal Reflux Disease (GERD)		
Erosive Esophagitis	40 mg	Once daily for 4 weeks
Maintenance therapy of Healing of Erosive Esophagitis	20 mg	Once daily
H. pylori eradication (Esomeprazole MUPS tablet with Amoxicillin and Clarithromycin)	20 mg	Twice daily for 7 days

Not recommended for the children under 12 years of age.

Take the tablet with or without food.

Injection:

Adult:

Gastroesophageal Reflux disease: 40 mg once daily; **Symptomatic reflux disease without esophagitis, treatment of NSAID-associated gastric ulcer and prevention of NSAID-associated gastric or duodenal ulcer:** 20 mg daily.

Children:

1-11 years: 10-20 mg once daily.

12-17 years: 20-40mg once daily.

Impaired Renal Function: Dose adjustment is not required in patients with impaired renal function.

Impaired Hepatic Function: Dose adjustment is not required in patient with mild to moderate liver impairment. For patients with severe liver impairment, a maximum daily dose of 20 mg should not be exceeded.

Elderly: Dose adjustment is not required in the elderly patient.

OR AS DIRECTED BY THE PHYSICIAN.

Direction for the Use of IV Injection: A solution for injection is prepared by adding 5 ml of 0.9% sodium Chloride solution to the vial for intravenous use. The reconstituted solution should be given as an intravenous injection over a period of at least 3 minutes.

Direction for Use of IV Infusion: A solution for intravenous infusion is prepared by adding first 5ml of 0.9% sodium chloride solution and further dilutes the resulting solution to a final volume of 50 ml. The reconstituted solution should be given as an intravenous infusion over a period of 10-30 minutes.

CONTRAINDICATIONS

Contraindicated in those patients who have known hypersensitivity to Esomeprazole or any other components of the formulation.

WARNING AND PRECAUTIONS

Esomeprazole should be used carefully if the patients have severe liver dysfunction and severe renal impairment. Taking a proton pump inhibitor like Esomeprazole may slightly increase the risk of hip, neck and spine fracture, particularly when it has been taken over a period of more than a year.

SIDE EFFECTS

Common: Headache, abdominal pain, constipation, flatulence, nausea or vomiting.

Rare: Abnormal liver function, aggressive behavior, anemia, blurred vision, bronchospasm.

USE IN PREGNANCY & LACTATION

Esomeprazole should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. The excretion of Esomeprazole in human milk has not been studied, so a decision should be made whether to discontinue nursing of the drug, taking into account the importance of the drug to the mother.

DRUG INTERACTION

With Medicine: Do not prescribe Esomeprazole MUPS tablet if the patient takes Nelfinavir, Atazanavir, Clopidogrel, Ketoconazole, Itraconazole, Voriconazole, Erlotinib, Citalopram, Imipramine or Clomipramine, Diazepam, Phenytoin, Warfarin, Cilostazole, Cisapride, Digoxin, Methotrexate, Tacrolimus and Rifampicin.

With Food: Esomeprazole does not react with food.

OVERDOSE

Seek medical attention from your physician.

STORAGE

Store below 30° C & dry place, protected from light.

Keep all medicines out of reach of children.

PACKING

Maxima® 20 Tablet (140's): Each Box contains 10×14 tablets in alu-alu blister strips.

Maxima® 40 Tablet (40's): Each Box contains 4×10 tablets in alu-alu blister strips.

Maxima® 20 Capsule (140's): Each Box contains 10×14 capsules in alu-alu blister strips.

Maxima® 40 Capsule (40's): Each Box contains 4×10 capsules in alu-alu blister strips.

Maxima® IV Injection: Each box contains 1 vial of lyophilized Esomeprazole 40 mg and 1 ampoule of 5 ml 0.9% Sodium Chloride injection in blister strip & 5 ml sterile disposable syringe.

Maxima® MUPS 20 Tablet: Each box contains 5×10 tablets in Alu-Alu blister strips.

Maxima® MUPS 40 Tablet: Each box contains 3×10 tablets in Alu-Alu blister strips.

* Further information is available on request.



Manufactured by:

The ACME Laboratories Ltd.
Dhulivita, Dhamrai, Dhaka, Bangladesh

For Health, Vigour and Happiness