

# Maxima®

Tablet  
Capsule  
IV Injection



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.

## Description

Maxima® (Esomeprazole) is a proton pump inhibitor and the S-isomer of Omeprazole. It suppresses gastric acid secretion by inhibiting the proton pump in the gastric parietal cell thus reduces gastric acidity. Daily dose of 20 mg to 40 mg leads to inhibition of gastric acid secretion.

## Indications

Healing of Erosive Esophagitis, Maintenance of Healing of Erosive Esophagitis, Symptomatic Treatment of Gastroesophageal Reflux Disease, Risk Reduction of NSAID-Associated Gastric Ulcer, *Helicobacter pylori* associated Ulcer, Zollinger-Ellison Syndrome and other hyper acidic complications.

## Dosage And Administration

Tablet/ Capsule :

Adults : Gastroesophageal Reflux Disease

Healing of Erosive Esophagitis: 20 or 40 mg once daily for 4-8 weeks, followed by a further 4-8 weeks if not fully healed. Maintenance of Healing of Erosive Esophagitis: 20 mg once daily. Symptomatic Treatment of Gastroesophageal Reflux Disease: 20 mg once daily for 4 weeks. An additional 4 weeks of treatment may be considered if symptoms do not resolve completely. Risk Reduction of NSAID-Associated Gastric Ulcer: 20 mg or 40 mg once daily for up to 6 months. *Helicobacter pylori* Associated Ulcer: One MAXIMA® 20, Amoxicillin (Moxilin) 1 g & Clarithromycin (Claricin) 500 mg all twice daily for 10 days. Zollinger-Ellison Syndrome: 40 mg twice daily.

Injection :

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 :

Tablet/ Capsule:

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

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

Injection: No data available for the children.

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

Impaired hepatic function: Dose adjustment is not required in patients 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 Use Of IV Injection :** A solution for intravenous use 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 5 ml 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 to 30 minutes.

## Contraindications

Contraindicated in case of known hypersensitivity to any component of the product.

## Precautions

When gastric ulcer is suspected, the possibility of gastric malignancy should be excluded before starting treatment with Esomeprazole.

## Use In Pregnancy & Lactation

There are no adequate and well controlled studies in pregnant women. 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 or the drug, taking into account the importance of the drug to the mother.

## Side Effects

Common side effects include nausea, vomiting, diarrhea, constipation, abdominal pain, flatulence and headache. In rare cases pruritus, urticaria, dizziness and dry mouth may appear.

## Drug Interaction

Esomeprazole may interfere with the absorption of drugs where gastric pH is an important determinant of bioavailability such as Ketoconazole, Iron Salts and Digoxin.

## Supply

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

Maxima® 40 Tablet: Each box contains 4 X 10 tablets in alu-alu blister strips.

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

Maxima® 20 Capsule (70's): Each box contains 5 X 14 capsules in alu-alu blister strips.

Maxima® 40 Capsule: Each box contains 4 X 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 & a 5 ml sterile disposable syringe.

Store in a cool & dry place, protected from light.

Keep all medicines out of reach of children.

\* Further information is available on request.



Manufactured by:

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

ISO 9001: 2015 Certified Company

# Maxima® MUPS

Tablet

## Esomeprazole

### COMPOSITION

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

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

### MUPS

MUPS is abbreviation for Multiple-Unit Pellet System. MUPS tablet is the most recent technologically advanced tablet that combine the advantages of both tablets and pellet-filled capsules in one dosage form.

### PHARMACOLOGY

Esomeprazole is a proton pump inhibitor that suppresses gastric acid secretion by inhibition of the H<sup>+</sup>/K<sup>+</sup> -ATPase in the gastric parietal cell thus reducing gastric acidity. After oral administration, peak plasma levels (C<sub>max</sub>) occur at approximately 1.5 hours (T<sub>max</sub>). 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.

### ADVANTAGE OF ESOMEPRAZOLE MUPS TABLET COMPARED TO CONVENTIONAL MODIFIED-RELEASE ESOMEPRAZOLE TABLETS AND PELLET-FILLED ESOMEPRAZOLE CAPSULES

1. Ensures greater bioavailability
2. Ensures uniform emptying of micro pellets from stomach into small intestine facilitates rapid dissolution and drug release resulting in early T<sub>max</sub> and C<sub>max</sub>
3. Ensures lesser possibility of dose dumping
4. Faster onset of action and ensures prolong therapeutic benefit
5. Ensures uniform drug release
6. Once daily dosing
7. Can be taken before or after meal
8. Ensures better and more uniform drug absorption
9. Reduces esophageal residence time better than capsules
10. Minimizes fluctuation in plasma concentration of drug

### PHARMACODYNAMIC ADVANTAGES

1. MUPS ensure rapid and uniform gastric emptying and subsequently uniform drug dissolution of pellets in the gastrointestinal tract due to their smallest size and larger surface area. Therefore uniform drug absorption is facilitated which results in consistent and controlled pharmacological action.
2. The number of pellets per MUPS dosage form is much more than a conventional pellet-filled capsule thus possibility of dose dumping in stomach and incomplete drug release is further minimized.

### INDICATIONS

1. Gastroesophageal Reflux Disease (GERD)
2. NSAID-associated gastric ulcer
3. *H. pylori* eradication (Triple Therapy)
4. Zollinger-ellison syndrome

### DOSEAGE AND ADMINISTRATION

**Route of Administration:** Orally.

**Adult (from age of 18):**

Indication	Dose	Frequency
<b>Gastroesophageal Reflux Disease (GERD)</b>		
Erosive esophagitis	40 mg	Once daily for 4 weeks
Maintenance therapy of healing of erosive esophagitis	20 mg	Once daily
<b>NSAID-associated gastric ulcer</b>	20 mg	Once daily for 4 to 8 weeks

<b><i>H. pylori</i> eradication (Esomeprazole MUPS tablet with Amoxicillin and Clarithromycin)</b>	20 mg	Twice daily for 7 days
<b>Zollinger-ellison syndrome</b>	40 mg to 80 mg	Twice daily

### 12 to 17 years old:

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

**Not recommended for the children under 12 years of age.**  
Take the tablet with or without food.

### 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 take Nelfinavir, Atazanavir, Clopidogrel, Ketoconazole, Itraconazole, Voriconazole, Erlotinib, Citalopram, Imipramine or Clomipramine, Diazepam, Phenytoin, Warfarin, Cilostazole, Cisapride, Digoxine, 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® MUPS 20:** Each box contains 5×10 tablets in Alu-Alu blister strips.

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

**\* Further information is available on request.**



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For Health, Vigour and Happiness

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