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. It is the more recent and challenging technologies 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 specific 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 extensively metabolized in the liver by the cytochrome P450 (CYP) 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.

CLINICAL 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 of enteric coating and drug release resulting in early T_{max} and C_{max} (peak time and peak plasma concentration)
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 and possibility of dose dumping (in stomach) and incomplete drug release is further minimized.

Indications

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

Dosage and Administration

Route of Administration: Orally.

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
Stomach ulcer caused by NSAIDs	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

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

Esomeprazole MUPS tablet is 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, wrist 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

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 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: There are no specific food that must exclude from diet when receiving this medication.

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.***

Manufactured by:
The ACME Laboratories Ltd.
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For Health, Vigour and Happiness