

Composition

Each MUPS (Multiple-Unit Pellet System) tablet contains Esomeprazole 15% w/w enteric coated pellets (as Esomeprazole Magnesium Trihydrate USP) equivalent to 20 mg Esomeprazole.

MUPS

MUPS is abbreviation for Multiple-Unit Pellet System. However, from pharmaceutical industry and research perspective, the term in general refers to MUPS compacted into tablets. Thus, the resulting tablets prepared by compaction of modified release coated multi particulates of pellets are called as MUPS. 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}). At repeated once- daily dosing with 40 mg, the systemic bioavailability is approximately 90%. 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

- Ensures greater bioavailability
- 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)
- Ensure lesser possibility of dose dumping
- Is a combination of fast acting and sustained action
- Ensures uniform drug release
- Once daily dosing
- Ensures lesser chance of localized irritation
- Ensures better and more uniform drug absorption
- Is better than capsules in reducing the esophageal residence time
- Minimizes fluctuation in plasma concentration of drug

Pharmacodynamic Advantages

MUPS ensure rapid and uniform gastric emptying and subsequently uniform drug dissolution of pellets in the gastrointestinal tract due to their small size and larger surface, uniform drug absorption is facilitated which results in consistent and controlled pharmacological action. A further reduction in inter and intra-subject variability in drug absorption and clinical response is facilitated since the number of pellets per MUPS dosage form is much more than a conventional pellet-filled tablet and possibility of dose dumping (in stomach) and incomplete drug release is further minimized.

Indications

- Gastroesophageal Reflux Disease (GERD)
- Risk Reduction of NSAID-associated gastric ulcer
- H.pylori eradication (Triple Therapy)
- Zollinger-Ellison Syndrome

Dosage & 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-80 mg	Once daily

12 to 17 years old

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Contraindication

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

Precaution

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

Side Effect

Common: Headache, abdominal pain, constipation, flatulence, nausea or vomiting. **Rare:** Abdominal 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 takes Nelfinavir, Atazanavir, Clopidogrel, Ketoconazole, Itraconazole, Voriconazole, Erlotinib, Citalopram, Imipramine or Clomipramine, Diazepam, Phenytoin, Warfarin, Cilostazole, Cisapride, Digoxin, Methotrexate, Tacrolimus and Rifampicin.

With Food: There are no specific foods that must exclude from diet when receiving this medication.

Overdose

Seek medical attention from your physician.

Storage

Store at temperature below 30° C in a dry place. Protect from light & moisture. Keep out of reach of children.

Packaging

Nexe MUPS Tablet : Each box contains 3x10's tablets in Alu-Alu blister pack.