

Emep MUPS

Esomeprazole Magnesium USP

COMPOSITION

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

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

MUPS

MUPS is the abbreviation for Multiple-Unit Pellet System. However, from pharmaceutical industry and research perspective, the term in general refers to pellets compacted into tablets. Thus, the resulting tablets prepared by compaction of modified release coated multiparticulates or pellets are called 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, the S-isomer of Omeprazole, reduces gastric acid secretion through specific inhibition of the acid pump in the parietal cell, where it is concentrated and converted to the active form in the acid environment of the secretory canaliculi and inhibits the enzyme H⁺K⁺ATPase -the acid pump.

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) • Ensures lesser possibility of dose dumping • Ensures uniform drug release • Once daily dosing • Ensures better and more uniform drug absorption • Minimizes fluctuation in plasma concentration of drug.

PHARMACODYNAMIC ADVANTAGES

• MUPS ensures 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 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 capsule and possibility of dose dumping (in stomach) and incomplete drug release is further minimized.

INDICATION

• **Gastroesophageal reflux disease (GERD):** Treatment of erosive reflux - Maintenance of healed oesophagitis to prevent recurrence - Symptomatic treatment of gastroesophageal reflux • **Eradication of *Helicobacter pylori* in combination with appropriate antibiotics:** - At the healing of *Helicobacter pylori* associated duodenal ulcer - For the prevention of relapse of *Helicobacter pylori* associated peptic ulcers • **Patients who have required a continuous NSAID treatment:** - At the healing of NSAID-associated gastric ulcers - For the prevention of NSAID associated gastric and duodenal ulcers in patients at risk • **Duodenal and gastric ulcer** • **Zollinger-Ellison syndrome.**

DOSAGE & ADMINISTRATION



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.

1. Swallow the tablet whole with glass of water. The tablet must not be chewed or crushed. or 2. If the patients have trouble swallowing the tablets, put the tablet into a glass of water (Do not use other liquids). Stir the preparation until the tablet disintegrate. Then drink the liquid within 30 minutes. Stir the mixture just always before drinking.	 
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This tablet can be taken before or after meal.

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.

CONTRAINDICATION

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

PRECAUTION

Esomeprazole tablet should be used carefully if the patient has severe liver dysfunction and severe renal impairment.

SIDE-EFFECTS

More frequent: Headache, abdominal pain, diarrhoea, flatulence, nausea/ vomiting and Less frequent: Dermatitis, pruritus, urticaria & dizziness.

USE IN PREGNANCY AND LACTATION

Manufacturer advices caution and there is no information available. It is not known whether Esomeprazole is excreted in breast milk.

STORAGE

• Store below 30°C, keep in dry place & protect from light.
• Keep out of reach of children.

PACKAGING

Emep MUPS 20 Tablet: Each box contains 60 tablets in Alu-Alu blister pack.

Emep MUPS 40 Tablet: Each box contains 30 tablets in Alu-Alu blister pack.

Manufactured by:

ARISTOPHARMA LTD.
Shampur-Kadamtali I/A, Dhaka-Bangladesh

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