

Composition:

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

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

Pharmacology:

MUPS is the abbreviation for Multiple Unit Pellet System. However, from pharmaceutical industry and research perspective, the term in general refers to MUPS compacted into tablets. It is a pharmaceutical solid dosage form produced by compressing a mixture of drug-containing pellets and powder excipients. MUPS is one of the more recent and challenging technologies that combine the advantages of both tablets and pellet-filled capsules in one dosage form.

Indication:

- Gastro-esophageal Reflux Disease (GERD)
- Risk reduction in NSAID associated gastric ulcer
- *H. pylori* eradication (Triple therapy)
- Zollinger-Ellison syndrome and idiopathic hypersecretion

Dose and administration:

Esomeprazole MUPS tablets should be swallowed whole with liquid. The tablets should not be chewed or crushed.

If required, the tablets can also be dispersed in half a glass of non-carbonated water (mineral water is not suitable). No other liquids should be used. Stir until the tablets disintegrate and drink the liquid with the pellets immediately or within 30 minutes. Rinse the glass with half a glass of water and drink. The pellets must not be chewed or crushed.

Indication	Adult (≥18 years)		Children & adolescents (12-18 years)	
	Dose	Frequency	Dose	Frequency
Gastro-esophageal Reflux Disease (GERD)				
Erosive Esophagitis	40 mg	Once daily for 4 weeks	40 mg	Once daily for 4 weeks
Maintenance of healing of Erosive Esophagitis	20 mg	Once daily	20 mg	Once daily
Risk reduction in NSAID associated gastric ulcer	20 mg	Once daily for 4-8 weeks	—	—
<i>H. pylori</i> eradication (Esomeprazole MUPS tablet with 1000 mg Amoxicillin and 500 mg Clarithromycin)	20 mg	Twice daily for 7 days	20 mg	Twice daily for 7 days
Zollinger-Ellison syndrome & idiopathic hypersecretion	(40-80) mg	Twice daily	—	—

Children 1-11 years:

Gastro-esophageal Reflux Disease (GERD) & Erosive esophagitis

Weight <20 kg: 10 mg once daily for 8 weeks

Weight ≥20 kg: 10 mg or 20 mg once daily for 8 weeks

Maintenance of healing of erosive esophagitis

10 mg once daily

Children below the age of 1 year:

Esomeprazole MUPS tablet is not approved for use in children younger than 1 year of age.

Hepatic Insufficiency

No dosage adjustment is recommended for patients with mild to moderate hepatic insufficiency. However, in patients with severe hepatic insufficiency a dose of 20 mg once daily should not be exceeded.

Renal Insufficiency

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

Contra-indication:

Esomeprazole is contraindicated in patients with known hypersensitivity to any component of the formulation.

Warning & precaution:

Esomeprazole should be used carefully if the patient has 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 is taken over a period of more than one year.

Side effects:

The most frequently occurring adverse events reported with Esomeprazole include headache, diarrhea, nausea, flatulence, abdominal pain, constipation and dry mouth. There are no difference in types of related adverse events seen during maintenance treatment upto 12 months compared to short term treatment.

Use in pregnancy & lactation:

Manufacturer advises caution. It is not known if Esomeprazole or its metabolites appear in human breast milk.

Use in children & adolescents:

Esomeprazole MUPS tablet is not approved for use in children younger than 1 year of age. Dose adjustment is not required in the elderly.

Drug interaction:

With medicine: Esomeprazole is extensively metabolized in the liver by CYP2C19 and CYP3A4. In vitro and in vivo studies have shown that Esomeprazole is not likely to inhibit CYPs 1A2, 2A6, 2C9, 2D6, 2E1 and 3A4. No clinically relevant interactions with drugs metabolized by these CYP enzymes would be expected. Drug interaction studies have shown that Esomeprazole does not have any clinically significant interactions with Phenytoin, Warfarin, Quinidine, Clarithromycin or Amoxicillin.

Esomeprazole may potentially interfere with CYP2C19, the major Esomeprazole metabolizing enzyme. Co-administration of Esomeprazole 30 mg and Diazepam, a CYP2C19 substrate has resulted in a 45% decrease in clearance of Diazepam. Increased plasma levels of Diazepam have been observed 12 hours after dosing and onwards. Esomeprazole inhibits gastric acid secretion. Therefore, Esomeprazole may interfere with the absorption of drugs where gastric pH is an important determinant of bioavailability (e.g., Ketoconazole, Iron salts and Digoxin).

Co-administration of Oral Contraceptives, Diazepam, Phenytoin, or Quinidine do not seem to change the pharmacokinetic profile of Esomeprazole.

Co-administration of Esomeprazole, Clarithromycin, and Amoxicillin has resulted in an increase in the plasma levels of Esomeprazole and 14-Hydroxycarithromycin.

With food & others: Food intake delays & decreases the absorption of Esomeprazole.

Overdose:

Patients ingesting an overdose of Esomeprazole (280 mg) have demonstrated symptoms that included weakness, loose stools & nausea.

Storage:

Store in a cool and dry place below 30°C, protect from light & moisture. Keep out of the reach of children.

Packing:

Esomups™ 20 Tablet: Each box contains 60 MUPS tablets in Alu-Alu blister packs.

Esomups™ 40 Tablet: Each box contains 30 MUPS tablets in Alu-Alu blister packs.

TM = Trade Mark

Manufactured by:

Jenphar Bangladesh Ltd.
Sreepur, Gazipur, Bangladesh