

Esover MUPS 20 Tablet Insert

180 mm X 260 mm

PACKAGE LEAFLET: INFORMATION FOR THE USER

Esover™ MUPS



Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

COMPOSITION

Esover MUPS 20 Tablet: Each MUPS tablet contains gastro resistant Multiple Unit Pellet System as Esomeprazole Magnesium Trihydrate USP equivalent to Esomeprazole 20 mg.

Esover MUPS 40 Tablet: Each MUPS tablet contains gastro resistant Multiple Unit Pellet System as Esomeprazole Magnesium Trihydrate USP equivalent to Esomeprazole 40 mg.

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. 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.

INDICATIONS

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

DOSAGE & 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		
H. pylori 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 and 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.

USE IN PREGNANCY & LACTATION

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

CONTRAINDICATIONS

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

SIDE EFFECTS

The most frequently occurring adverse events reported with Esomeprazole include headache, diarrhoea, 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.

WARNING AND 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.

DRUG INTERACTION

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.

Combination Therapy with Clarithromycin

Co-administration of esomeprazole, clarithromycin, and amoxicillin has resulted in increases in the plasma levels of esomeprazole and 14-hydroxylarithromycin.

HOW TO STORE ESOVER MUPS

Keep out of the reach and sight of children. Store at temperature not exceeding 30°C in a dry place. Protect from light & moisture. Keep this medicine in the original container/box. Do not take your medicine after the expiry date (EXP) shown on the packing materials. The expiry date refers to the last day of that month.

AVAILABILITY

Esover MUPS 20 Tablet: Each box contains 3X10's MUPS tablets in Alu-Alu blister pack.

Esover MUPS 40 Tablet: Each box contains 3X10's MUPS tablets in Alu-Alu blister pack.

Manufactured by:

Veritas Pharmaceuticals Ltd.

Vannara, Mouchak, Kaliakoir, Gazipur, Bangladesh.

TM - Trade Mark.