

Esobest MUPS

Esomeprazole

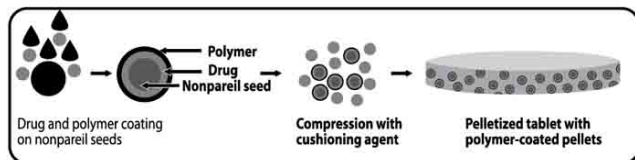
COMPOSITION :

Esobest MUPS 20 Tablet: Each MUPS tablet contains 133.333 mg (15% w/w) of Esomeprazole enteric coated pellets equivalent to 20 mg Esomeprazole (as Esomeprazole Magnesium Trihydrate USP).

Esobest MUPS 40 Tablet: Each MUPS tablet contains 266.67 mg (15% w/w) of Esomeprazole enteric coated pellets equivalent to 40 mg Esomeprazole (as Esomeprazole Magnesium Trihydrate USP).

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 multiparticulates or 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.



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

MODE OF ACTION:

The proton pump inhibitor Esomeprazole inhibits gastric acid by blocking the hydrogen-potassium adenosine triphosphatase enzyme system (the proton pump) of the gastric parietal cell. Proton pump inhibitors are effective for short-term treatment of gastric and duodenal ulcers. Esomeprazole is also used in the prevention and treatment of NSAID associated gastric ulcers.

INDICATIONS:

- Gastroesophageal reflux disease (GERD): - Treatment of erosive reflux.
- Maintenance of healed oesophagitis to prevent recurrences.
- Symptomatic treatment of gastroesophageal reflux.
- 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 AND ADMINISTRATION:

Esomeprazole MUPS Tablet can be taken with or without food.

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
Gastric ulcer caused by NSAIDs	20 mg	Once daily for 4 to 8 weeks
Zollinger-Ellison Syndrome	40-80 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

Children 1-11 years:

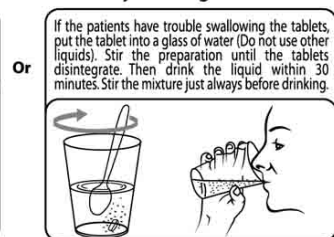
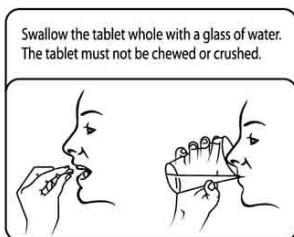
If children have trouble swallowing the tablet, it can be mixed with some water. Children should drink the mixture immediately.

Gastro-esophageal Reflux Disease (GERD)

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

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

It is not recommended for the children under 1 year of age.



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.

USE IN PREGNANCY AND LACTATION:

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

DRUG INTERACTION:

Esomeprazole is a CYP2C19 inhibitor. When starting or stopping treatment with Esomeprazole should be taken into account potential interactions with medicines through CYP2C19 metabolized.

STORAGE:

Store in a cool and dry place, protected from light. Keep out of reach of children.

PACKING:

Esobest MUPS 20 Tablet: Each box contains 3 pouches and each pouch contains 10 tablets in Alu-Alu blister strip.

Esobest MUPS 40 Tablet: Each box contains 3 pouches and each pouch contains 10 tablets in Alu-Alu blister strip.

Manufactured by:



Sharif Pharmaceuticals Ltd.

Rupganj, Narayanganj, Bangladesh