

Nexum[®] MUPS 20

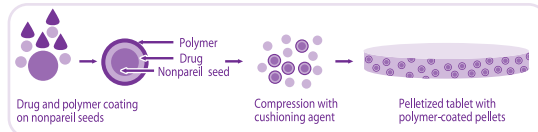
Esomeprazole 20 mg

COMPOSITION

Each MUPS (Multiple-Unit Pellet System) tablet contains 133.333 mg Esomeprazole 15.0% 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 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.

INDICATION

- Gastroesophageal Reflux Disease (GERD) • Risk Reduction of NSAID-associated gastric ulcer • *H. pylori* eradication (Triple therapy) • 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
<i>H. pylori</i> 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
<i>H. pylori</i> eradication (Esomeprazole MUPS tablet with Amoxicillin and Clarithromycin)	20 mg	Twice daily for 7 days

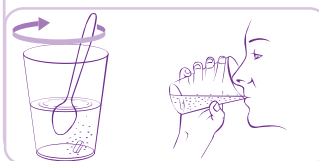
Esomeprazole MUPS Tablet is not recommended for the children under 12 years of age.

Swallow the tablet whole with a glass of water. The tablet must not be chewed or crushed.



Or

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 tablets disintegrate. Then drink the liquid within 30 minutes. Stir the mixture just always before drinking.



Take the tablet with or without food.

CONTRAINDICATION

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

WARNING AND PRECAUTION

Esomeprazole MUPS tablet should be used carefully if the patient has 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.

USE IN PREGNANCY AND LACTATION

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

SIDE EFFECT

Headache, abdominal pain, constipation, flatulence, nausea or vomiting.

DRUG INTERACTION

Do not prescribe Esomeprazole MUPS tablet if the patient take Nelfinavir, Atazanavir, Clopidogrel, Ketoconazole, Itraconazole, Voriconazole, Erlotinib, Citalopram, Imipramine or Clomipramine, Diazepam, Phenytoin, Warfarin, Cilostazol, Cisapride, Digoxin, Methotrexate, Tacrolimus and Rifampicin.

STORAGE

Store in a cool (below 30° C) and dry place, protected from light and moisture.

HOW SUPPLIED

Each box contains 30 tablets in Alu-Alu blister pack.

Manufactured by



SQUARE
FORMULATIONS LTD.
Tangail, Bangladesh

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