

Nexum[®] MUPS

Esomeprazole

COMPOSITION

Nexum[®] MUPS 20 Tablet: Each MUPS tablet contains 20 mg Esomeprazole (as Esomeprazole Magnesium Trihydrate USP enteric coated pellets).

Nexum[®] MUPS 40 Tablet: Each MUPS tablet contains 40 mg Esomeprazole (as Esomeprazole Magnesium Trihydrate USP enteric coated pellets).

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 Tmax and Cmax (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): - Treatment of erosive reflux. - Maintenance of healed oesophagitis to prevent recurrences. - 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

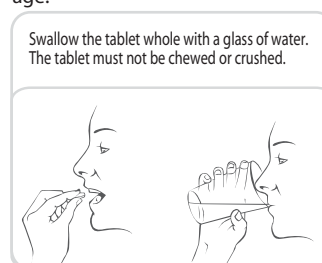
Adult from age of 18:

| 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 |

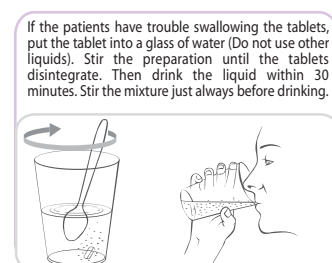
12 to 17 years old:

| 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.



Or



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.

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 (below 30⁰ C) and dry place, protected from light and moisture.

HOW SUPPLIED

Nexum[®] MUPS 20 Tablet: Each box contains 50 tablets in Alu-Alu blister pack.

Nexum[®] MUPS 40 Tablet: Each box contains 30 tablets in Alu-Alu blister pack.

Manufactured by



SQUARE

PHARMACEUTICALS LTD.
BANGLADESH