

Esotem MUPS

Esomeprazole

COMPOSITION:

Esotem[®] MUPS 20 Tablet: Each MUPS (Multiple Unit Pellet System) tablet contains Esomeprazole Magnesium Trihydrate USP equivalent to Esomeprazole 20 mg as enteric coated pellets.

Esotem[®] MUPS 40 Tablet: Each MUPS (Multiple Unit Pellet System) tablet contains Esomeprazole Magnesium Trihydrate USP equivalent to Esomeprazole 40 mg as 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 pellets compacted into tablets. Thus, the resulting tablets prepared by compaction of modified release coated multiparticulates or pellets are called MUPS. It is one of the latest and challenging technologies that combine the advantages of both tablets and pellet filled capsules in one dosage form.

PHARMACOLOGY:

Esomeprazole, the S-isomer of Omeprazole, reduces gastric acid secretion through specific inhibition of the acid pump in the parietal cell, where it is concentrated and converted to the active form in the acidic environment and inhibits the H⁺/K⁺ ATPase enzyme of the gastric parietal cells.

INDICATION:

- Gastroesophageal Reflux Disease (GERD).
- Healing of NSAID associated gastric ulcer.
- H.Pylori eradication triple therapy.
- Zollinger-Elison Syndrome and idiopathic hypersecretion.

DOSAGES & ADMINISTRATION:

Adult over 18 years of age:

Indication	Dose	Frequency
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 mg to 80 mg	Twice daily
H. Pylori eradication (Esomeprazole MUPS tablet with Amoxicillin and Clarithromycin)	20 mg	Twice daily for 7 days

12 to 17 years old:

Indication	Dose	Frequency
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

Children 1 to 11 years old:

Indication	Dose	Frequency
Erosive Esophagitis (Weight <20 kg or Weight ≥20 kg)	10 mg/20 mg	Once daily for 8 weeks
Maintenance therapy of healing of Erosive Esophagitis	10 mg	Once daily

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. **This tablet can be taken before or after meal.**

CONTRAINDICATIONS:

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.

SIDE-EFFECTS:

More frequent: Headache, abdominal pain, diarrhoea, flatulence, nausea & vomiting and Less frequent: Dermatitis, pruritus, urticaria & dizziness.

USE IN PREGNANCY AND LACTATION:

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

USE IN CHILDREN & ADOLESCENTS:

Children below the age of 1 year: Esotem MUPS tablet is not approved for use in children younger than 1 year.

DRUG INTERACTION:

Possible interaction with Clopidogrel, Atazanavir, Ketoconazole, Itraconazole, Voriconazole, Erlotinib, Citalopram, Imipramine, Clomipramine, Diazepam, Phenytoin, Warfarin and Cilostazol.

STORAGE:

Store in a dry and cool place below 30° C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:

Esotem[®] MUPS 20 Tablet: Each box contains 5x10's tablets in Alu-Alu blister pack.

Esotem[®] MUPS 40 Tablet: Each box contains 3x10's tablets in Alu-Alu blister pack.



Manufactured by

Team Pharmaceuticals Ltd.

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