

Esocon

Esomeprazole

COMPOSITION

Esocon MUPS 20 mg Tablet: Each MUPS (Multiple-Unit Pellet System) tablet contains 133.334 mg Esomeprazole 15% w/w enteric coated pellets (as Esomeprazole Magnesium Trihydrate USP) equivalent to 20 mg Esomeprazole.

Esocon 20 mg Capsule: Each capsule contains Esomeprazole magnesium trihydrate USP equivalent to Esomeprazole 20 mg.

Esocon 40 mg Capsule: Each capsule contains Esomeprazole magnesium trihydrate USP equivalent to Esomeprazole 40 mg.

Esocon 40 mg IV Injection: Each vial contains sterile Lyophilized Esomeprazole sodium INN equivalent to 40 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 multi-particulates or pellets are called 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 Tablet and Pellet-filled Esomeprazole capsules

- Ensures greater bioavailability
- Ensures uniform emptying of micro pellets from stomach in to 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
- Ensuring lesser chance of localized irritation
- Ensures better and more drug absorption
- Is better than capsule in reducing the esophageal residence time
- Minimizes fluctuation of plasma concentration of drug

Pharmacodynamic Advantage

- MUPS ensures rapid and uniform gastric emptying subsequently uniform drug dissolution of pellets in the gastrointestinal track due to their small size and large surface, uniform drug absorption is facilitated which results in consistent and controlled pharmacological action.
- A further reduction in intra and inter 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 pellets-filled capsule and possibility of dose dumping (in stomach) and incomplete drug release is further minimized.

Indication

Esomeprazole is indicated for the treatment of the following diseases:

1. Gastric ulcer, 2. Duodenal ulcer, 3. Healing of Erosive Esophagitis
4. Long-term management of esophagitis
5. Symptomatic Gastroesophageal Reflux Disease (GERD)
6. H. pylori Eradication for treatment of Duodenal Ulcer. (Triple Therapy with Esomeprazole, clarithromycin and amoxicillin)
7. NSAID-induced gastric ulcers

Dosage and administration

Gastric ulcer: 20 - 40 mg once daily, Duodenal ulcer: 20 - 40 mg once daily

Healing of Erosive Esophagitis : 20 mg or 40 mg once daily for 4 to 8 Weeks. For those patients who have not healed after 4-8 weeks of treatment, an additional 4-8 weeks course of Esomeprazole may be considered.

Long-term management of esophagitis : 20 mg once daily.

Symptomatic Gastroesophageal Reflux Disease: 20 mg once daily for 4 weeks.

H. pylori Eradication for treatment of Duodenal Ulcer : Triple Therapy : 20 mg Esomeprazole once daily with 500 mg clarithromycin twice daily, and 1 g amoxicillin twice daily for 7-10 days. NSAID-induced peptic ulcers: 20 - 40 mg once daily.

Injection:

Duodenal ulcer, gastric ulcer, gastrointestinal lesions refractory to H2 blockers, Zollinger-Ellison syndrome	40 mg per day Intravenously
Reflux Esophagitis	20-40 mg per day Intravenously

Direction for reconstitution of solution

Solution for injection is prepared by adding 5 ml of water for injection or 10 ml sodium chloride 0.9% Solution for intravenous injection into the vial containing the dry powder .The reconstituted solution for injection is clear to colorless to very slightly yellow.

Contra-indication

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

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 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.

Side Effects

Side effects reported with Esomeprazole include headache, constipation, flatulence, nausea or vomiting and abdominal pain.

Use in Pregnancy and Lactation

There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed. The excretion of Esomeprazole in human milk has not been studied

Drug Interactions

Esomeprazole inhibits gastric acid secretion. Therefore, Esomeprazole may interfere with the absorption of drugs where gastric pH is an important determinant of bioavailability (eg. ketoconazole, iron salts and digoxin).

Overdose

There is no experience to data with deliberate overdose. Data are limited but single doses of 80 mg Esomeprazole were uneventful. Esomeprazole is extensively plasma protein bound and is therefore not readily dialyzable. As in any case of overdose, treatment should be symptomatic and general supportive measures should be utilized.

Storage

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

Commercial Pack

Esocon MUPS 20 mg Tablet: Each box contains 5 x 10 tablets in alu-alu blister pack.

Esocon 20 mg Capsule: Each box contains 10 x 10 capsules in alu-alu blister pack.

Esocon 40 mg Capsule: Each box contains 6 x 10 capsules in alu-alu blister pack.

Esocon 40 mg IV Injection: Each box contains 1 Vial of Esomeprazole sodium & 1 ampoule of 5 ml sterile Water for Injection BP or 1 ampoule of 10 ml sterile Sodium chloride 0.9% solution.

Esocon 40 mg IV injection is Manufactured by Popular Pharmaceuticals Ltd. for Biopharma Ltd.

Manufactured by



For further query on the use of this medicine, consult to a registered Doctor or Pharmacist.