

# Esotem<sup>®</sup>

Esomeprazole USP

## COMPOSITION:

Esotem<sup>®</sup> 20 Capsule: Each enteric coated capsule contains Esomeprazole Magnesium Trihydrate USP equivalent to Esomeprazole 20 mg.

Esotem<sup>®</sup> 40 Capsule: Each enteric coated capsule contains Esomeprazole Magnesium Trihydrate USP equivalent to Esomeprazole 40 mg.

## PHARMACOLOGY:

Esotem<sup>®</sup> is the magnesium salt of esomeprazole which is the S enantiomer of Omeprazole and belongs to the class of proton pump inhibitors. Esomeprazole works by preventing the final step in gastric acid production by covalently binding to the (H<sup>+</sup>, K<sup>+</sup>)-ATPase enzyme at the secretory surface of gastric parietal cell, thus reduce acid secretion. Esomeprazole has 97% plasma protein binding profile which converts into a 1.5 hours plasma elimination half-life. Esotem<sup>®</sup> is mainly excreted in urine.

## INDICATION:

Treatment of Gastroesophageal Reflux Disease (GERD)

-Healing of Erosive Esophagitis

-Maintenance of Healing of Erosive Esophagitis

-Symptomatic Gastroesophageal Reflux Disease H. pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence Zollinger Ellison Syndrome

Acid Related Dyspepsia: Duodenal and Gastric Ulcer

## DOSAGE & ADMINISTRATION:

Esotem<sup>®</sup> capsule should be swallowed whole and taken at least one hour before meal. The majority of patients are healed within 4 to 8 weeks. For patients who do not heal after 4-8 weeks, an additional 4-8 weeks of treatment may be considered. If symptoms do not resolve completely after 4 weeks, an additional 4 weeks of treatment may be considered. Directions for reconstitution of solution:

Solution for injection is prepared by adding 5 ml of 0.9% Sodium Chloride for Intravenous injection Into the vial containing the dry powder. The reconstituted solution for injection is clear and colorless to very slightly yellow.

Administration IV injection must be administered Intravenously over a period of at least 3 minutes. Half of the IV injection should be used when 20 mg is to be administered. Prepared solution must be used within 12 hours of preparation and can be exposed to normal indoor lighting at a maximum of 30° C.

Geriatric: No dosage adjustment is necessary. Renal Insufficiency: No dosage adjustment is necessary. Hepatic Insufficiency: No dosage adjustment is necessary in patients with mild to moderate liver impairment. For patients with severe liver impairment, a dose of 20 mg of Esotem should not be exceeded.

## CONTRA-INDICATION:

Esomeprazole is contraindicated in patients with known hypersensitivity to any component of the formulation or to substituted Benzimidazole.

## WARNING AND PRECAUTION:

Symptomatic response to therapy with Esomeprazole does not preclude the presence of gastric malignancy. Atrophic gastritis has been noted occasionally in gastric corpus biopsies from patients treated long-term with omeprazole, of which Esomeprazole is an enantiomer.

## SIDE EFFECTS:

In general, Esomeprazole was well tolerated in both short and long-term clinical trials. The most frequently occurring adverse events (>1%) are headache and diarrhea. Nausea, flatulence, abdominal pain, constipation and dry mouth occurred at similar rates among patients taking Esomeprazole.

## USE IN PREGNANCY & LACTATION:

Pregnancy: Pregnancy category B. Esomeprazole should be used during pregnancy only if the potential benefit to pregnant women justifies the potential risk to the fetus.

Lactation: There are no adequate and well-controlled studies on the release of Esomeprazole in human milk. Thus, a decision should be taken to discontinue nursing or to discontinue the drug, taking into account the Importance of the drug to the mother.

## USE IN CHILDREN & ADOLESCENTS:

Use of Esomeprazole in pediatric and adolescent patients 1 to 17 years of age for short-term treatment of GERD is supported by safety and pharmacokinetic studies performed in pediatric and adolescent patients. The safety and effectiveness of esomeprazole for the treatment of symptomatic GERD in patients <1 year of age and for other pediatric uses have not been established.

## DRUG INTERACTION:

Drug interaction studies have shown that Esomeprazole does not have any clinically significant interact one with Phenytoin, Warfarin, Quinidine, Clarithromycin or Amoxicillin. 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). Co-administration of oral contraceptives, Diazepam, Phenytoin or Quinidine did not seem to change the pharmacokinetic profile of Esomeprazole.

## OVERDOSE:

If you take too much: You could have dangerous levels of the drug in your body. Symptoms of an overdose of this drug can include: Confusion, drowsiness, blurred vision, fast heart rate, nausea, sweating, flushing (reddening and warming of your face), headache, dry mouth. Single doses of 80 mg esomeprazole were uneventful. No specific antidote is known. As in any case of overdose, treatment should be symptomatic and general supportive measures should be utilized.

## 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<sup>®</sup> 20 capsule: Each box contains 5x15's capsule in Alu-Alu blister pack.

Esotem<sup>®</sup> 40 capsule: Each box contains 3x10's capsule In Alu-Alu blister pack.