

Anti-peptic Ulcerants

ESOREST TABLETS

COMPOSITION:

Each Enteric coated tablet contains:

Esomeprazole Magnesium...20 mg

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PHARMACOLOGY:

ESOREST (Esomeprazole) is the proton pump inhibitor (PPI) that suppresses gastric acid secretion by specific inhibition of the H^+/K^+ in the gastric parietal cell. ESOREST IS THE FIRST SINGLE ISOMER PPI DEVELOPED FOR THE TREATMENT OF ACIDRELATED DISEASES.

The S- and R – isomer are protonated and converted in the acidic compartment of the parietal cell forming the active inhibitor, the achiral sulphenamide.

By acting specifically on the proton pump, ESOREST blocks the final step in acid production, thus reducing gastric acidity. This effect is dose- related up to a daily dose of 20 – 40 mg and leads to inhibition of gastric acid secretion.

The AUC after administration of a single 40 mg dose of ESOREST is decreased by 33 – 53 % after food intake compared to fasting conditions. ESOREST should be taken at least one hour before meals.

ESOREST is extensively metabolised in the liver by the cytochrome P450(CYP) enzyme system .The metabolites lack antisecretory activity. ESOREST is 97% bound to plasma proteins. The plasma elimination half life of ESOREST is approximately 1 – 1.5 hr. Less than 1 % parent drug is excreted in the urine. Approximately 80 % of an oral dose of ESOREST is excreted as inactive metabolites in the urine , the remainder found as inactive metabolites in feces.

INDICATIONS :

A.ESOREST is indicated for GERD including:

- Treatment of erosive reflux esophagitis
- Long-term management of patients with healed esophagitis
- Symptomatic treatment of GERD
- ESOREST, in combination with appropriate antibiotics, for the eradication of *H. pylori*
- Healing of *H. pylori*-associated duodenal ulcer

CONTRAINDICATIONS:

ESOREST is contraindicated in patients with previous hypersensitivity reactions to the drug, a component of the product formulation or to substituted benzimidazole.

DRUG INTERACTIONS:

Changes in gastric pH can affect bioavailability of certain medications. (e.g Ketoconazole, Iron salts) ESOREST can decrease the clearance of Diazepam by 45% and increase the plasma levels of Diazepam. No drug -drug interaction found between esomeprazole and phenytoin, r-warfarin, quinidine, amoxicillin, and clarithromycin.

PRECAUTIONS:

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

PREGNANCY AND LACTATION:

There are no adequate and well controlled studies in pregnant women. Sporadic reports have been received of congenital abnormalities occurring in infants born to women who have received omeprazole during pregnancy. Omeprazole classified as Pregnancy Category C. The manufacturer recommends that Omeprazole only be used during pregnancy if the potential benefit justifies the potential risk to foetus. Esomeprazole is classified as Pregnancy Category B.

ADVERSE REACTIONS:

The adverse events associated with esorest therapy are similar to those seen with placebo and omeprazole therapy. this is also similar to other PPIs available. The most common adverse events reported in the clinical trials were diarrhea, abdominal pain, flatulence, gastritis, nausea, and headache.

DOSAGE AND ADMINISTRATIONS:

Treatment of erosive esophagitis: ESOREST 40mg once daily for 4 – 8 weeks

Symptomatic GERD/Maintenance of erosive esophagitis: 20 mg once daily for 4 weeks

H.pylori : 40 mg once daily for 10 days in combination with appropriate antibiotics

PRESENTATIONS:

ESOREST is available as an enteric coated and easy-to-swallow small tablet available in strip of 10 tablets.