

## COMPOSITION:

**Esogel 20 Tablet:** Each enteric coated tablet contains Esomeprazole Magnesium Trihydrate USP equivalent to Esomeprazole 20 mg.

**Esogel 40 Tablet:** Each enteric coated tablet contains Esomeprazole Magnesium Trihydrate USP equivalent to Esomeprazole 40 mg.

**Esogel 20 Capsule:** Each capsule contains Esomeprazole Magnesium Trihydrate USP equivalent to 20 mg Esomeprazole as enteric coated pellets.

**Esogel 40 Capsule:** Each capsule contains Esomeprazole Magnesium Trihydrate USP equivalent to 40 mg Esomeprazole as enteric coated pellets.

## DESCRIPTION:

Esomeprazole is a proton pump inhibitor that suppresses gastric acid secretion by specific inhibition of the H<sup>+</sup>/K<sup>+</sup>ATPase enzyme in the gastric parietal cells.

## INDICATIONS:

Esogel is indicated for the healing of erosive esophagitis, maintenance of healing of erosive esophagitis, symptomatic gastroesophageal reflux disease (GERD), *H. pylori* eradication to reduce the duodenal ulcer recurrence, Zollinger-Ellison syndrome, acid-related dyspepsia, duodenal and gastric ulcer, risk reduction of NSAID associated gastric ulcer.

## DOSAGE & ADMINISTRATION:

Esogel tablet/capsule is for oral administration, and should be taken one hour before meal. The recommended dosage schedule for Esogel tablet/capsule is to be followed as below or as per advice of the registered physician.

**Healing of erosive esophagitis:** 20 mg or 40 mg of Esogel once daily for 4 to 8 weeks. For patients do not heal within 4 to 8 weeks, an additional 4 to 8 weeks treatment may be considered.

**Maintenance of healing of erosive esophagitis:** 20 mg once daily, not to extend more than 6 months.

**Symptomatic GERD:** 20 mg once daily for 4 weeks. If symptoms do not completely resolve, an additional 4 weeks treatment may be considered.

**Zollinger-Ellison syndrome:** 40 mg twice daily dosage is to be adjusted individually and to be continued as long as clinically indicated.

**Acid-related dyspepsia:** 20 to 40 mg once daily for 2 to 4 weeks according to response.

**Duodenal ulcer:** 20 mg once daily for 2 to 4 weeks.

**Gastric ulcer:** 20 to 40 mg once daily for 4 to 8 weeks.

***H. pylori* eradication to reduce the duodenal ulcer recurrence:** 2 tablets/capsules of 20 mg or 1 tablet/capsule of 40 mg Esomeprazole, 1 g Amoxicillin and Clarithromycin 500 mg two times daily for 10 days.

**Risk reduction of NSAID associated gastric ulcer:** 20 mg or 40 mg once daily.

## CONTRAINDICATIONS:

Esomeprazole is contraindicated to the patients with known hypersensitivity to any component of the formulation.

## WARNINGS & PRECAUTIONS:

Symptomatic response to therapy with Esomeprazole does not preclude the presence of gastric malignancy.

## SIDE-EFFECTS:

Generally Esomeprazole is well-tolerated in both long-term and short-term therapy. However frequent adverse effects like headache, diarrhea, nausea, flatulence, abdominal pain, constipation and dry mouth occur at similar rates among patients receiving Esomeprazole for treatment.

## USE IN PREGNANCY & LACTATION:

There are no adequate and well-controlled studies with Esomeprazole in pregnant women. There are no clinical data on the effects of Esomeprazole on the breastfed infant or on milk production. The developmental and health benefits of breastfeeding should be considered along with the mothers' clinical need for Esomeprazole and any potential adverse effects on the breastfed infant from Esomeprazole or from the underlying maternal condition.

## DRUG INTERACTIONS:

Esomeprazole inhibits gastric acid secretion, therefore, Esomeprazole may interfere with the absorption of drugs where gastric P<sup>H</sup> is an important determinant of bioavailability like Ketoconazole, Iron salt and Digoxin. Co-administration of oral contraceptive, Diazepam, Phenytoin or Quinidine did not seem to change the pharmacokinetic profile of Esomeprazole.

## STORAGE:

Store below 30°C Temperature in a dry place. Keep away from light. Keep out of the reach of children.

## PACKING:

**Esogel 20 Tablet:** Each box contains 100 tablets in Alu-Alu blister strip.

**Esogel 40 Tablet:** Each box contains 50 tablets in Alu-Alu blister strip.

**Esogel 20 Capsule:** Each box contains 100 capsules in Alu-Alu blister strip.

**Esogel 40 Capsule:** Each box contains 50 capsules in Alu-Alu blister strip.

Manufactured by:

**Novatek Pharmaceuticals Ltd.**

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**NOVATEK**