

# ESOTOR

Esomeprazole

## COMPOSITION

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

**Esotor 20 Capsule:** Each capsule contains enteric coated pellets of Esomeprazole Magnesium Trihydrate BP equivalent to Esomeprazole 20 mg.

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

**Esotor 40 Capsule:** Each capsule contains enteric coated pellets of Esomeprazole Magnesium Trihydrate BP equivalent to Esomeprazole 40 mg.

## PHARMACOLOGY

Esotor (Esomeprazole) is a proton pump inhibitor that suppresses gastric acid secretion by specific inhibition of the H<sup>+</sup>/K<sup>+</sup>-ATPase in the gastric parietal cell. Esomeprazole (S-isomer of omeprazole) is the first single optical isomer of proton pump inhibitor, provides better acid control than racemic proton pump inhibitors.

## INDICATIONS

Treatment of Gastroesophageal Reflux Disease (GERD), Healing of erosive esophagitis, Maintenance of healing of erosive esophagitis, Symptomatic Gastroesophageal Reflux Disease (GERD). Reduction of NSAID-associated gastric ulcer and *H. pylori* eradication (Triple therapy).

## DOSAGE AND ADMINISTRATION

### Adult dosage schedule:

INDICATION	DOSE	FREQUENCY
Gastroesophageal Reflux Disease (GERD)		
Healing of erosive esophagitis	20 mg or 40 mg	Once daily for 4 to 8 weeks*
Maintenance of healing of erosive esophagitis	20 mg	Once daily**
Symptomatic GERD	20 mg	Once daily for 4 weeks***
Reduction of NSAID- associated gastric ulcer	20 mg or 40 mg	Once daily for up to 6 months**
<i>H. pylori</i> eradication (Triple therapy)		
Esomeprazole	20 mg	Twice daily for 10 days
Amoxicillin	1000 mg	Twice daily for 10 days
Clarithromycin	500 mg	Twice daily for 10 days

### Paediatric use (12 years and older):

**Short term treatment of GERD:** 20 mg or 40 mg once daily for up to 8 weeks.

\* 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 treatment may be considered.

\*\* Controlled studies did not extend beyond six months.

\*\*\* If symptoms do not resolve completely after 4 weeks, an additional 4 weeks of treatment may be considered.

## CONTRAINDICATIONS

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

## WARNING AND PRECAUTION

Exclude the possibility of malignancy when gastric ulcer is suspected and before treatment for dyspepsia. When using in combination with antibiotic, refer to the prescribing information of the respective antibiotics.

## SIDE EFFECTS

Side effects reported with Esomeprazole include headache, diarrhea and abdominal pain.

## USE IN PREGNANCY AND LACTATION

US FDA pregnancy category of Esomeprazole is C. So, Esomeprazole should be avoided in pregnancy and lactation unless the potential benefits to the other outweigh the possible risks to the fetus.

## USE IN CHILDREN AND ADOLESCENTS

The use of Esomeprazole in paediatric patients (1 to 17 years of age) for the short-term treatment (up to 8 weeks) of GERD is approved. The safety and effectiveness of Esomeprazole have not yet been established in paediatric patients <1 years of age.

## DRUG INTERACTIONS

Esomeprazole appears to be a selective inhibitor of the cytochrome P450 mono-oxygenase system, there may be an effect on hepatic clearance, but there have been no reports to date of clinically relevant interactions. There is some uncertainty over the effect of Esomeprazole on the oral combined contraceptive pill. Physiological changes similar to those found with omeprazole are likely to take place because of the reduction in gastric acid which is likely to influence the bacterial colonization of the stomach and duodenum and also vitamin B<sub>12</sub> absorption.

## OVERDOSAGE

Limited information is available on the effects of higher doses in man and specific recommendations for treatment cannot be given.

## STORAGE

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

## HOW SUPPLIED

**Esotor 20 Tablet:** Each box contains 50 tablets in Alu-Alu blister pack.

**Esotor 20 Capsule:** Each box contains 50 capsules in Alu-Alu blister pack.

**Esotor 40 Tablet:** Each box contains 30 tablets in Alu-Alu blister pack.

**Esotor 40 Capsule:** Each box contains 40 capsules in Alu-Alu blister pack.