

PRESCRIBING INFORMATION

# EPRAZOLE<sup>®</sup> Capsules

(Esomeprazole)

**COMPOSITION:**

**EPRAZOLE 20mg Capsules**

**Each capsule contains:**

Esomeprazole (as Esomeprazole Magnesium Trihydrate enteric coated pellets)....Brookes Specs....20mg  
Mfg. Specs. Brookes

**EPRAZOLE 40mg Capsules**

**Each capsule contains:**

Esomeprazole (as Esomeprazole Magnesium Trihydrate enteric coated pellets)....Brookes Specs....40mg  
Mfg. Specs. Brookes

**DESCRIPTION:**

EPRAZOLE (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. The S- and R-isomers of omeprazole 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, EPRAZOLE (Esomeprazole) blocks the final step in acid production, thus reducing gastric acidity. This effect is dose-related up to a daily dose of 20 to 40 mg and leads to inhibition of gastric acid secretion.

**PHARMACOLOGY:**

EPRAZOLE (Esomeprazole) should be taken at least one hour before meals. Bioavailability is approximately 90% (repeated once-daily dosing) and 64% (single dose). Food decreases AUC by 43% to 53%. EPRAZOLE (Esomeprazole) is 97% protein bound. Vd is approximately 16 L (at steady state). EPRAZOLE (Esomeprazole) is metabolized in the liver to inactive metabolites, the metabolites of Esomeprazole lack anti-secretory activity. The half-life is approximately 1 to 1.5 h. Less than 1% of parent drug excreted in urine; approximately 80% excreted as inactive metabolites in the urine, and the remainder is found in feces.

**INDICATIONS:**

EPRAZOLE (Esomeprazole) is indicated for the following

- Gastroesophageal Reflux Disease (GERD)
- Healing & Maintenance of Erosive Esophagitis
- Symptomatic Gastroesophageal Reflux Disease
- Gastric and Duodenal ulcers
- Risk reduction in NSAID induced gastric ulcers
- As triple therapy regimen in H-Pylori eradication

**DOSAGE AND ADMINISTRATION:**

EPRAZOLE (Esomeprazole) capsules should be swallowed whole and taken at least one hour before meals.

**Recommended Dosage Schedule**

Capsule 20mg or 40mg	Gastroesophageal Reflux Disease (GERD)	Once daily for 4 to 8 weeks (an additional 4-8 weeks treatment may be considered if symptoms persist or esophagitis does not heal)
Capsule 20mg or 40mg	Healing & Maintenance of Erosive Esophagitis	Once daily
Capsule 20mg or 40mg	Symptomatic Gastroesophageal Reflux Disease	Once daily for 4 weeks (an additional 4-8 weeks treatment may be considered if symptoms does not resolve completely)
Capsule 20mg or 40mg	Gastric and Duodenal ulcers	Once daily
Capsule 20mg	Risk reduction in NSAID induced Gastric ulcers	Once daily
Capsule 40mg	As triple therapy regimen in H-Pylori eradication	Once daily for 10-14 days along with other medications

**CONTRAINDICATION:**

EPRAZOLE (Esomeprazole) is contraindicated in patients with known hypersensitivity to active agent or any component of the formulation.

**SIDE-EFFECTS:**

EPRAZOLE is usually very well tolerated. The following side-effects have been reported during therapy of EPRAZOLE (Esomeprazole) e.g. headache, abdominal pain, diarrhea, flatulence, nausea, vomiting, constipation, dermatitis, pruritus, urticaria, dizziness, dry mouth, hypersensitivity reactions e.g. angioedema, anaphylactic reaction, paraesthesia, somnolence, insomnia, vertigo, reversible mental confusion, agitation, aggression, depression and hallucinations, gynaecomastia, leukopenia, thrombocytopenia, agranulocytosis, pancytopenia, increased liver enzymes, rash, photosensitivity, erythema multiforme, increased sweating, peripheral oedema, blurred vision, taste disturbance and hyponatraemia.

**DOSAGE IN SPECIAL POPULATIONS:**

**Geriatric:** Dose adjustment based on age is not necessary.

**Hepatic insufficiency:** In patients with moderate to severe hepatic insufficiency, a dose of 20mg once daily should not be exceeded.

**Renal insufficiency:** In patients with renal impairment, no dose adjustment is required.

**Pregnancy:** There are no adequate and well-controlled studies in pregnant women. EPRAZOLE (Esomeprazole) should be used during pregnancy only if clearly needed or on the advice of the physician.

**Nursing mothers:** EPRAZOLE (Esomeprazole) should be taken on the advice of the physician as Esomeprazole is likely to be excreted in human milk.

**PRECAUTIONS:**

In case of any unintentional weight loss, recurrent vomiting, dysphagia, haematemesis or melaena and when gastric ulcer is suspected or present, malignancy should be excluded, as treatment with EPRAZOLE (Esomeprazole) may alleviate symptoms and delay diagnosis.

When prescribing EPRAZOLE (Esomeprazole) for eradication of Helicobacter Pylori infection, possible drug interactions for other components in the triple therapy should be considered.

Patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption should not take this medicine.

**DRUG INTERACTIONS:**

EPRAZOLE (Esomeprazole) is used with caution in patients using ketoconazole, Itraconazole, diazepam, citalopram, imipramine, clomipramine, phenytoin etc., the plasma concentrations of these drugs may be increased and a dose reduction could be needed.

**STORAGE:**

Store at temperature below 30 °C away from light and moisture.

**PRESENTATION:**

EPRAZOLE-20mg Capsules is available in Alu-Alu blister packing of 2 x 7's, 4 x 7's & 14 x 7's Capsules.

EPRAZOLE-40mg Capsules is available in Alu-Alu blister packing of 2 x 7's, 4 x 7's & 14 x 7's Capsules.

**brookes**

**Manufactured by:**

Brookes Pharma Private Limited  
58 - 59 Sector 15 Korangi Industrial Area  
Karachi 74900 Pakistan

