

ESOSCOT Capsules

COMPOSITION: Each capsule contains:

Esomeprazole Magnesium Trihydrate Pellets * eq. to Esomeprazole 20 & 40 mg respectively.

DESCRIPTION: ESOSCOT Capsule is an enteric-coated pellet formulation of Esomeprazole Magnesium due to its acid labile nature. Esomeprazole (ESOSCOT) is the S-isomer of omeprazole, which inhibits the gastric acid secretion more effectively than omeprazole. Chemically esomeprazole is bis (5-methoxy-2- [(S)-[(4-methoxy-3, 5-dimethyl-2-pyridinyl) methyl] sulfinyl]-1H-benzimidazole-1-yl) magnesium trihydrate.

PHARMACOLOGY: Esomeprazole (ESOSCOT) acts by binding irreversibly to the H⁺/K⁺ ATPase in the proton pump, which dramatically decreases the secretion of HCl in the stomach & alters gastric pH. Peak plasma levels of Esomeprazole (ESOSCOT) are achieved approximately after 1.5 hours of oral administration. At repeated once daily dosing with 40 mg, the systemic bioavailability is approximately 90% compared to 64% after a single dose of 40 mg. Esomeprazole is 97% bound to plasma proteins. Esomeprazole is extensively metabolized in the liver by the cytochrome P450 (CYP) enzyme system. The metabolites of esomeprazole lack antisecretory activity. The plasma elimination half life of esomeprazole is approximately 1-1.5 hours. Less than 1% of parent drug is excreted in the urine. Approximately 80% of an oral dose of esomeprazole is excreted as inactive metabolites in the urine, and the remainder is found as inactive metabolites in the feces.

INDICATIONS: ESOSCOT (Esomeprazole) is indicated for:

- ▶ Gastroesophageal Reflux Disease (GERD).
 - Treatment of Erosive Reflux Esophagitis.
 - Long-term management of patients with healed esophagitis to prevent relapse.
 - Symptomatic treatment of Gastroesophageal Reflux Disease (GERD) without Esophagitis.
- ▶ As triple therapy Esomeprazole (ESOSCOT) plus Amoxicillin (Amoxascot) and Clarithromycin (Clariscot) for the treatment of patients with H. pylori infection and duodenal ulcer disease (active or history of within the past 5 years).
 - Healing of duodenal ulcer associated with helicobacter pylori infection.
 - Prevention of relapse of peptic ulcers in patients with Helicobacter pylori associated ulcers.

CONTRAINDICATIONS: ESOSCOT (Esomeprazole) is contraindicated in patients with known hypersensitivity to any content of the formulation or to substituted benzimidazoles.

POSSIBLE ADVERSE EFFECTS: The most frequently occurring adverse events with Esomeprazole therapy include, diarrhea, nausea, flatulence, abdominal pain, constipation and dry mouth. Other side effects include *Cardiovascular:* Hypertension & tachycardia. *Gastrointestinal:* Stomatitis and gastrointestinal candidiasis. *Nervous System/Psychiatric:* Confusion, depression, dizziness, nervousness, insomnia, paresthesia, somnolence, vertigo, agitation, aggression & hallucinations. *Endocrine:* Gynaecomastia. *Haematologic:* Leukopenia, thrombocytopenia, agranulocytosis & pancytopenia. *Hepatic:* increased liver enzymes, hepatitis with or without jaundice & hepatic failure. *Dermatologic:* Rash, photosensitivity, toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome, erythema multiforme & alopecia. Besides these, other adverse effects include malaise, hypersensitivity reactions like fever, bronchospasm, interstitial nephritis, increased sweating, peripheral edema, blurred vision, taste disturbance & hyponatraemia.

DRUG INTERACTIONS:

- ▶ Co-administration of Esomeprazole decreases the absorption of ketoconazole & itraconazole due to decreased intragastric acidity during treatment with esomeprazole.
- ▶ Co-administration of esomeprazole, clarithromycin, and amoxicillin has resulted in increases in the levels of

esomeprazole and 14-hydroxylclarithromycin.

- ▶ Esomeprazole may potentially interfere with CYP2C19, the major esomeprazole metabolizing enzyme, so co-administration of esomeprazole with other drugs metabolized by CYP2C19 enzyme such as diazepam, citalopram, imipramine, clomipramine, phenytoin, etc. results in increased plasma concentration of these drugs & needs dose reduction of such drugs.

WARNINGS: *Use in Pregnancy:* There are no well-controlled & adequate studies in pregnant women. Esomeprazole should be used during pregnancy, only if clearly needed. *Use in Lactation:* Esomeprazole is likely to be excreted in human milk, so esomeprazole should be used only if clearly needed during lactation. *Pediatric Use:* Safety & effectiveness of the drug has not been established in pediatric patients. *Use in Elderly:* No dosage adjustment required in elderly patients. *Use in Renal Failure:* In cases of severe renal failure the drug should be used with caution. *Hepatic Insufficiency:* In patients with mild to moderate hepatic insufficiency, no dosage adjustment is recommended. However in patients with severe hepatic insufficiency, a dose of 20 mg daily should not be exceeded.

DOSAGE AND ADMINISTRATION: ESOSCOT Capsules should be swallowed whole and should be taken at least one hour before meals. Adult dosage guidelines for ESOSCOT (Esomeprazole) Capsules are given in table below:

RECOMMENDED ADULT DOSAGE GUIDELINES		
INDICATION	DOSE	FREQUENCY
Gastroesophageal Reflux Disease (GERD)		
Healing of Erosive Esophagitis.	20 or 40 mg	Once daily for 4-8 weeks (An additional 4-8 week treatment may be considered if symptoms persist or esophagitis does not heal).
Maintenance of healing erosive esophagitis	20 mg	Once daily (controlled studies do not extend beyond 6 months)
Symptomatic treatment of Gastroesophageal Reflux Disease (GERD) without Esophagitis	20 or 40 mg	Once daily for 4 weeks (An additional 4-8 week treatment may be considered if symptoms persist & do not resolve completely).
H.Pylori eradication to reduce the risk of duodenal ulcer recurrence: ESOSCOT (Esomeprazole) Amoxascot (Amoxicillin) Clariscot (Clarithromycin)	40 mg 1000 mg 500 mg	Once daily for 10 days. <i>Twice daily for 10 days.</i> <i>Twice daily for 10 days.</i>

The drug should be used under strict medical supervision/advice.

STORAGE / PRECAUTIONS: Store in a cool, dry and dark place between 15-30 °C. Keep all medicines out of the children's reach.

PRESENTATION: ESOSCOT Capsules 20 & 40 mg are available in packing containing 14 capsules.



scotmann
PHARMACEUTICALS

Complete Medical Information available only for doctors on request.

Manufactured by:

SCOTMANN PHARMACEUTICALS

5-D, I-10/3 Industrial Area, Islamabad-Pakistan