

DESCRIPTION:

Esomeprazole is the S-isomer of Omeprazole. It reduces gastric acid secretion through a specific targeted mechanism of action. It is a specific inhibitor of the acid pump in the parietal cell.

COMPOSITION:

Esmotac-20 tablet:

Each enteric coated tablet contains Esomeprazole Magnesium USP equivalent to Esomeprazole 20 mg.

Esmotac-40 tablet:

Each enteric coated tablet contains Esomeprazole Magnesium USP equivalent to Esomeprazole 40 mg.

Esmotac-20 capsule:

Each delayed release capsule contains enteric coated pellets of Esomeprazole Magnesium USP equivalent to Esomeprazole 20 mg.

INDICATIONS:

Esomeprazole is indicated for the relief of heartburn and other symptoms associated with gastroesophageal reflux disease (GERD) and for the healing of erosive esophagitis, a potentially serious condition association with GERD. The FDA approved Esomeprazole for maintenance of healing of erosive esophagitis and in combination with Amoxicillin and Clarithromycin, for the eradication of Helicobacter Pylori infection in patients with duodenal ulcer disease.

DOSAGE AND ADMINISTRATION:

Recommended adult dosage schedule of Esmotac		
DISEASE	DOSE	FREQUENCY
Gastroesophageal reflux disease (GERD)	20 mg	Once daily for 4 weeks
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 gastroesophageal reflux disease	20 mg	Once daily for 4 weeks***
Helicobacter Pylori eradication to reduce the risk of duodenal ulcer recurrence triple therapy:		
Esmotac	40 mg	Once daily for 10 days
Amoxicillin	1000 mg	Twice daily for 10 days
Clarithromycin	500 mg	Twice daily for 10 days

*The majority of patients are healed within 4 to 8 weeks. For patients who do not heal after 4 to 8 weeks, an additional 4 to 8 weeks treatment may be considered.

**Controlled studies did not extend beyond 6 months.

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

CONTRAINDICATIONS:

Patients with known hypersensitivity to any component of the formulation.

ADVERSE REACTIONS:

Esomeprazole is well tolerated in both short and long-term use. Common adverse events are headache and diarrhoea. Other side effects include nausea, flatulence, abdominal pain, constipation and dry mouth.

SPECIAL PRECAUTION:

Geriatric: No dosage adjustment is necessary.

Paediatric: Safety and effectiveness in paediatric patients have not been established.

Renal insufficiency: No dosage adjustment is necessary in patients with mild to moderate liver impairment. For patients with severe liver impairment, a dosage of 20 mg of Esmotac should not be exceeded.

Gender: No dosage adjustment is necessary.

DRUG INTERACTIONS:

Esomeprazole inhibits gastric acid secretion. Therefore, Esomeprazole may interfere with the absorption of drugs where gastric pH is an important determinant of bioavailability (e.g. Ketoconazole, Iron salts and Digoxin).

Renal insufficiency: No dosage adjustment is necessary in patients with mild to moderate liver impairment. For patients with severe liver impairment, a dosage of 20 mg of Esmotac should not be exceeded.

Gender: No dosage adjustment is necessary.

DRUG INTERACTIONS:

Esomeprazole inhibits gastric acid secretion. Therefore, Esomeprazole may interfere with the absorption of drugs where gastric pH is an important determinant of bioavailability (e.g. Ketoconazole, Iron salts and Digoxin).

OVER DOSE:

There is no experience to data with deliberate over dose. Data are limited but single dose of 80 mg Esomeprazole were uneventful. Esomeprazole is extensively plasma protein bound and is therefore not readily dialyzable. As in any case of over dose, treatment should be symptomatic and general supportive measures should be utilized.

USE IN PREGNANCY AND LACTATION:

Pregnancy:

FDA approved pregnancy category B.

Esomeprazole should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing mothers:

There is no data on the excretion of Esomeprazole into human milk.

PHARMACEUTICAL PRECAUTION:

STORAGE:

Tablet:

Store below 30 °C, protected from light and wet place. Keep away from children.

Capsule:

Store below 25 deg C, protected from light and wet place. Keep away from children.

PACKING:

Esmotac-20 tablet: Each box contains 6 * 10' * s tablets in alu-alu blister pack.

Esmotac-40 tablet: Each box containing 3 * 10' : tablets in alu-alu blister pack.

Esmotac-20 Capsule: Each box containing 4 X14's / 3 X10's/6 X10's Capsules in alu-alu blister pack.