

OMEPLUS

(ESOMEPRAZOLE)

CAPSULES

DESCRIPTION

OMEPLUS capsules are an enteric-coated pellet formulation of Esomeprazole Magnesium.

COMPOSITION

OMEPLUS (Esomeprazole) is available for oral administration as:

OMEPLUS CAPSULES 20mg

Each capsule contains: Esomeprazole Magnesium Trihydrate (pellets) equivalent to Esomeprazole (USP).....20mg

OMEPLUS CAPSULES 40mg

Each capsule contains: Esomeprazole Magnesium Trihydrate (pellets) Equivalent to Esomeprazole (USP).....40mg

CLINICAL PHARMACOLOGY

MECHANISM OF ACTION

Esomeprazole works by binding irreversibly to the H⁺/K⁺-ATPase in the proton pump. Since the proton pump is the final pathway for secretion of hydrochloric acid by the parietal cells in the stomach. Its inhibition dramatically decreases the secretion of hydrochloric acid into the stomach.

PHARMACOKINETICS

ABSORPTION: At repeated once daily dosing with 40mg, the systemic bio-availability is approximately 90% compared to 64% after a single dose of 40mg.

EFFECT OF FOOD: Food delays and decreases the absorption of esomeprazole, but this does not significantly change its effect on the intragastric acidity.

METABOLISM: Esomeprazole is extensively metabolized in the liver by the cytochrome p450 (CYP) enzyme system. The metabolites of esomeprazole lack anti-secretory activity.

EXCRETION: Approximately 80% of an oral dose of esomeprazole is excreted as inactive metabolite in the urine, and the remainder is found as inactive metabolites in the faeces.

SPECIAL POPULATION

GERIATRIC: Dose adjustment based on age is not necessary.

PAEDIATRIC: The pharmacokinetics of esomeprazole have not been studied in patients < 18 years of age.

HEPATIC INSUFFICIENCY: No dose adjustment is necessary for patients with mild to moderate hepatic insufficiency (Child Pugh Classes A and B). However in patients with severe hepatic insufficiency (Child Pugh Class C) a dose of 20mg once daily should not be exceeded.

RENAL INSUFFICIENCY: The pharmacokinetics of esomeprazole in patients with renal impairment are not expected to be altered relatively to healthy volunteers, as less than 1% of esomeprazole is excreted unchanged in urine. So no dose adjustment is required.

INDICATIONS

OMEPLUS (Esomeprazole) is indicated for:

- GASTROESOPHAGEAL REFLUX DISEASE (GRED)**
 - Treatment & long term management of erosive reflux esophagitis.
 - Symptomatic treatment of gastroesophageal reflux disease (GRED) without esophagitis.
- AS A TRIPLE THERAPY FOR THE ERADICATION OF HELICOBACTER PYLORI.**
 - Healing of duodenal ulcer associated with helicobacter pylori infection.
 - Prevention of relapse of peptic ulcers in patients with helicobacter pylori associated ulcers.

DOSAGE AND ADMINISTRATION

OMEPLUS (Esomeprazole) capsules should be swallowed whole and taken at least one hour before meals. The recommended adult dosages are outlined below.

INDICATIONS	DOSE	FREQUENCY
Gastroesophageal Reflux Disease	OMEPLUS 20mg	Once daily for 4 weeks
Healing of Erosive Esophagitis	OMEPLUS 20mg to 40mg	Once daily for 4 to 8 weeks
Maintenance of Healing of Erosive Esophagitis	OMEPLUS 20mg	Once daily
NSAIDs induced Gastric Ulcer	OMEPLUS 20mg to 40mg	Once daily for up to 6 months
Helicobacter pylori Infection	OMEPLUS 40mg Amoxicillin 1000mg Clarithromycin 500mg	Once daily for 10 days Twice daily for 10 days Twice daily for 10 days

Note: For patients with severe liver impairment, a dose of 20mg of OMEPLUS (Esomeprazole) should not be exceeded.

ADVERSE REACTIONS

Following adverse reactions have been reported during therapy of esomeprazole. But none found to be dose related.

COMMON: Headache, abdominal pain, diarrhoea, flatulence, nausea / vomiting, constipation.

UNCOMMON: Dermatitis, pruritis, urticaria, dizziness, dry mouth.

RARE: Hypersensitivity reactions e.g.; Angioedema, anaphylactic reaction.

Also the following drug reactions have been observed for the recombine esomeprazole and may occur with esomeprazole:

CENTRAL AND PERIPHERAL NERVOUS SYSTEM: Paraesthesia, somnolence, insomnia, vertigo, reversible mental confusion, agitation, aggression, depression and hallucination, predominantly in severely ill patients.

ENDOCRINE: Gynaecomastia.

GASTROINTESTINAL: Stomatitis and gastrointestinal candidiasis.

HAEMOTOLOGICAL: Leukopenia, thrombocytopenia, agranulocytosis and pancytopenia.

HEPATIC: Increased liver enzymes, encephalopathy in patients with pre-existing severe liver diseases; hepatitis with or without jaundice, hepatic failure.

SKIN: Rash, photosensitivity, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN), alopecia.

OTHER: Malaise, hypersensitivity reactions e.g.; fever, bronchospasm, interstitial nephritis, increased sweating, peripheral oedema, blurred vision, taste disturbance and hyponatraemia.

CONTRAINDICATIONS

OMEPLUS (Esomeprazole) is contraindicated in patients with known hypersensitivity to drug or any components of the formulation.

PREGNANCY: There are no adequate and well-controlled studies in pregnant women. Esomeprazole should be used during pregnancy only if clearly needed.

NURSING MOTHERS: Because esomeprazole is likely to be excreted in human milk a decision should be made whether to discontinue nursing or to discontinue the drug.

DRUG INTERACTIONS

In common with the use of other inhibitors of acid secretion or antacids, the absorption of ketoconazole and itraconazole can decrease during treatment with esomeprazole due to decreased intragastric acidity during treatment with esomeprazole.

INSTRUCTIONS

Store below 30°C. Protect from heat, light & moisture. Keep all medicines out of the reach of children. To be sold on the prescription of a registered medical practitioner only.

PRESENTATION

OMEPLUS (Esomeprazole) capsules 20mg & 40mg are available in the Alu-Alu packs of 2x7's.

اومی پلس
کیپسول
(ایس اوسپرازول)

ہدایات: دوا کو 30°C سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ گرمی، روشنی اور نمی سے محفوظ رکھیں۔
تمام دوائیں بچوں کی پہنچ سے دُور رکھیں۔ صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔



Manufactured by:
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