

Cisec

(OMEPRAZOLE) USP

CAPSULES

DESCRIPTION

CISEC (Omeprazole) a substituted benzimidazole, is a proton pump inhibitor that inhibits gastric acid secretion.

QUALITATIVE & QUANTITATIVE COMPOSITION

CISEC (Omeprazole) is available for oral administration as:

CISEC Capsule 20mg

Each capsule contains: Enteric coated pellets of Omeprazole eq. to Omeprazole (SPL Specs.).....20mg

CISEC Capsule 40mg

Each capsule contains: Enteric coated pellets of Omeprazole eq. to Omeprazole (SPL Specs.).....40mg

CLINICAL PHARMACOLOGY

MECHANISM OF ACTION

Omeprazole reduces gastric acid secretion through a unique mechanism of action. Omeprazole belongs to a new class of anti-secretory compounds, the substituted benzimidazoles that do not exhibit anti-cholinergic or histamine antagonistic properties. It inhibits secretion of gastric acid by irreversibly blocking the enzyme system of hydrogen/potassium adenosine tri-phosphatase, the proton pump of the gastric parietal cell. This effect is dose-related and leads to inhibition of both basal and stimulated acid secretion irrespective of the stimulus.

PHARMACOKINETICS

ABSORPTION/DISTRIBUTION: Omeprazole is acid-labile and is administered orally as enteric-coated pellets in capsules. Omeprazole is rapidly but variably absorbed following oral administration, with peak plasma levels of omeprazole occurring within 0.5 to 3.5 hours. Absorption of omeprazole is not affected by food and also appears to be dose dependent. Increasing the dosage above 40mg has been reported to increase the plasma concentrations in a non-linear fashion because of saturation of first pass metabolism. Absorption is higher after long term administration. The systemic bio-availability of omeprazole is approximately 35%. After repeated once daily administration, the bio-availability increases to about 60%. The plasma protein binding is approximately 95%.

METABOLISM & EXCRETION: Following absorption, omeprazole is almost completely metabolized in the liver, primarily by the cytochrome P450 isoenzyme CYP2C19 to form hydroxy-omeprazole and to a small extent by CYP3A to form omeprazole sulfone. These metabolites are inactive and excreted mostly in the urine and to a lesser extent in the bile. The majority of the dose (about 77%) is eliminated in the urine and the remainder, recoverable in the feces. The elimination half-life from plasma is reported to be about 0.5 to 3 hours.

SPECIAL POPULATION

PEDIATRIC: Available data from children (1 year and older) suggest that the pharmacokinetics within the recommended doses are similar to those reported in adults. At steady state, lower plasma levels of omeprazole were seen in some children.

GERIATRIC: The bio-availability of omeprazole may be increased in elderly patients.

RENAL INSUFFICIENCY: The systemic bio-availability of omeprazole is not significantly altered in patients with reduced renal function. Therefore dose adjustment is not required.

HEPATIC INSUFFICIENCY: The area under the plasma concentration-time curve is increased in patients with impaired liver function, but no tendency to accumulation of omeprazole has been found.

THERAPEUTIC INDICATIONS

CISEC (Omeprazole) is indicated for the treatment of:

- **Gastro-Esophageal 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).
- Gastric and duodenal ulcer.
- Treatment and prophylaxis of NSAID-associated ulceration.
- Eradication of Helicobacter pylori infection associated with peptic ulcer disease.
- Zollinger-Ellison syndrome.
- Dyspepsia.
- Prophylaxis of acid aspiration.

DOSAGE & ADMINISTRATION

(Omeprazole) capsule is given by mouth, which should be swallowed whole and not crushed or chewed.

SYMPTOMATIC GASTRO-ESOPHAGEAL REFLUX DISEASE (GERD) WITHOUT ESOPHAGITIS: The recommended adult oral dose is 20mg daily for up to 4 weeks.

EROSIVE ESOPHAGITIS: The recommended adult oral dose for the treatment of patients with erosive esophagitis and accompanying symptoms due to GERD is 20mg daily for 4 to 8 weeks.

MAINTENANCE OF HEALING OF EROSIVE ESOPHAGITIS: The recommended adult oral dose is 20 mg daily.

DOSAGE FOR CHILDREN IN GERD: In children, doses in the ranges 0.7 to 1.4mg per kg body weight daily, up to a maximum daily dose of 40mg have been given for 4 to 12 weeks.

GASTRIC AND DUODENAL ULCER: A single daily dose of 20mg by mouth or 40mg in severe cases is given. Treatment is continued for 4 weeks for duodenal ulcer and 8 weeks for gastric ulcer. Where appropriate, a dose of 10 to 20mg once daily may be given for maintenance.

NSAID-ASSOCIATED ULCERATION: Doses of 20mg daily are used in the treatment of NSAID-associated ulceration. A dose of 20mg daily may also be used for prophylaxis in patients with a previous history of gastroduodenal lesions who require continued NSAID treatment.

HELICOBACTER PYLORI ERADICATION: For the eradication of H. Pylori in peptic ulceration omeprazole 40mg daily may be combined with anti-bacterials in dual.

INSTRUCTIONS

Store at 15-30°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

CISEC Capsule 20mg: Available in Alu-Alu blister packing of 2x7s.

CISEC Capsule 40mg: Available in Alu-Alu blister packing of 2x7s.

سی سیک کیپسول

(اومپرازول) بلیسٹرن

ہدایات: دوا کو 15-30° سینٹی گریڈ پر رکھیں۔

گرمی، روشنی اور نمی سے بچائیں۔ تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

صرف مندرجہ ذیل کے نسخہ پر فروخت کریں۔



Manufactured by:

STANDPHARM PAKISTAN (PVT) LTD.

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