

Loe-h Capsule

Omeprazole 20mg Oral

لوک ایچ پیول
 اینڈیا پرائیویٹ لمیٹڈ

Each capsule contains:

Omeprazole (as enteric coated pellets) M.S. 20mg

Product Complies with Rakel's Specs.

PROPERTIES: Loe-h (Omeprazole) is supplied as delayed-release capsule for oral administration containing Omeprazole as enteric-coated pellets that disintegrate only in alkaline environment of the intestine. Loe-h suppresses the secretion of gastric acid by the irreversible inhibition of the enzyme system H⁺K⁺ ATPase (also called proton pump) of the gastric parietal cells. It is one of the most potent inhibitors of gastric acid secretion.

Pharmacokinetics: Loe-h is rapidly absorbed from the intestines and peak plasma levels are obtained within 0.5 to 3.5 hours. Protein binding is approximately 95%. The absolute bioavailability is about 30-40%. Although the half life of omeprazole is only 0.5-1 hour. The body takes around 24 hours to synthesize new proton pumps. Therefore the acid suppression lasts for more than 24 hours. Major route of elimination of the drug is urinary tract.

INDICATIONS:

- Duodenal ulcer;
- Gastric ulcer;
- NSAID-associated gastric and duodenal ulcer;
- Reflux esophagitis;
- Symptomatic gastro esophageal reflux disease (GERD) (i.e., Heartburn and regurgitation);
- Dyspepsia a complex of symptoms which may be caused by any one of the organic diseases listed above, or upon investigation no identifiable organic cause is found (i.e., Functional dyspepsia);
- Zollinger-Ellison syndrome (pathological) hypersecretory condition);
- Eradication of H. pylori;

Loe-h, in combination with clarithromycin and either amoxicillin or metronidazole, is indicated for the treatment of patients with peptic ulcer disease associated with Helicobacter pylori infection.

CONTRAINDICATIONS: Loe-h is contraindicated in patients with a known hypersensitivity to the drug or any component of the formulation.

PRECAUTIONS: The daily dose in elderly patients and in patients with severe liver disease should, as a rule, not exceed 20mg. Loe-h should be taken before meals. Capsules should not be opened, chewed or crushed and should be swallowed whole.

DRUG INTERACTION: Loe-h affects the metabolism of the drugs metabolized via hepatic cytochrome P450 system it therefore increases concentration of the drug metabolized through this system e.g. Diazepam, phenytoin, warfarin, etc. The concomitant use of Loe-h with these drugs should be avoided. Use during pregnancy and lactation is not recommended unless absolutely essential. Safety and effectiveness have not been established for pediatric patients less than 2 years of age.

ADVERSE EFFECTS

The following adverse events have been reported in individuals receiving omeprazole capsules: diarrhoea, headache, flatulence, abdominal pain, constipation and dizziness/vertigo. In addition, the following adverse events were also reported from routine use:

Skin: Rash, rash and/or pruritis. In isolated cases photosensitivity, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN) and alopecia.

Musculoskeletal: In isolated cases: arthralgia, muscular weakness and myalgia.

Central and Peripheral Nervous System: Rarely dizziness, paraesthesia, somnolence, insomnia and vertigo. In isolated cases reversible mental confusion, agitation, depression and hallucination occurring predominantly in severely ill patients.

Gastrointestinal: Nausea and vomiting. In isolated cases dry mouth, stomatitis and gastrointestinal candidiasis.

Hepatic: In rare cases, increased liver enzymes levels. In isolated cases encephalopathy in patients with pre-existing severe liver disease, hepatitis with or without jaundice and hepatic failure.

Endocrine: In isolated cases gynaecomastia.

Other: In isolated cases, patients have developed leucopenia, agranulocytosis and pancytopenia.

Other: Rarely malaise, hypersensitivity reactions including urticaria (rarely) and, in isolated cases, angioedema, fever, bronchospasm and interstitial nephritis and anaphylactic shock. In isolated cases increased sweating, peripheral edema, blurred vision, taste disturbances and hyponatraemia.

DOSE AND ADMINISTRATION:

Duodenal Ulcer:	
Acute Therapy:	20mg once daily, for up to 4 weeks.
Refractory Patients:	20mg-40mg once daily, for up to 4 weeks.
Maintenance Therapy:	20mg-40mg once daily as necessary.
Gastric Ulcer:	
Acute Therapy:	20mg once daily, for 4-8 weeks.
Refractory Patients:	40mg once daily, for 8 weeks.
Maintenance Therapy:	20mg once daily, increased to 40mg once daily as necessary.
Reflux Esophagitis:	
Acute Therapy:	20mg once daily, for 4-8 weeks.
Refractory Patients:	40mg once daily, for up to 8 weeks.
Maintenance Therapy:	20mg once daily; in recurrence, dose can be increased to 40mg once daily.
Symptomatic Gastroesophageal Reflux Disease	
	20mg given once daily, for up to 4 weeks

NSAID-Associated Gastric or Duodenal Ulcers

Acute Therapy: 20mg once daily for 4-8 weeks
 For the prevention of relapse 20mg once daily for up to 6 months

Dyspepsia: 20mg once daily for up to 4 weeks

Helicobacter pylori Associated Peptic Ulcer

Omeprazole, Amoxicillin and Clarithromycin Triple Therapy: The recommended dose for eradication of H. Pylori is Omeprazole 20mg, amoxicillin 1000mg and clarithromycin 500mg, all twice daily for seven days.

Omeprazole, Metronidazole and Clarithromycin Triple Therapy: The recommended dose for eradication of H. Pylori is Omeprazole 20mg, Metronidazole 500mg and clarithromycin 250mg, all twice daily for seven days.

To ensure healing and/or symptom control, further treatment with 20mg Loe-h once daily for up to three weeks is recommended for patients with active duodenal ulcer, and with 20-40mg Loe-h once daily for up to twelve weeks for patients with active gastric ulcer.

Zollinger-Ellison Syndrome

The dose used in the treatment of Zollinger-Ellison Syndrome will vary with individual patient.

STORAGE:

- Store at a temperature between 15-30°C
- Protect from light and moisture.
- Keep out of children's reach.

PRESENTATION:

Loe-h Capsules (Omeprazole) is available in a pack of 14 Capsules.



Manufactured by:
REKO PHARMACAL (Pvt.) LTD.
 13-km, Multan Road, Lahore-Pakistan
www.rekopharmaceutical.com

