

Eupi

Omeprazole BP

Description

Eupi (Omeprazole) a substituted benzimidazole, is an inhibitor of gastric acid secretion. It inhibits gastric acid secretion by blocking hydrogen-potassium-adenosine triphosphatase ($H^+/K^+ATPase$) enzyme system in the gastric parietal cell. After oral administration, the onset of the antisecretory effect occurs within one hour, with the maximum effect occurring within two hours and inhibition of secretion lasts up to 72 hours. When the drug is discontinued, secretory activity returns gradually over 3 to 5 days.

Composition

Eupi 20 Capsule: Each capsule contains Omeprazole BP 20 mg as enteric coated pellets.

Eupi 40 Capsule: Each capsule contains Omeprazole BP 40 mg as enteric coated pellets.

Eupi IV Injection: Each vial contains Omeprazole 40 mg as sterile lyophilized Omeprazole Sodium BP.

Indications

It is indicated for treatment of gastric & duodenal ulcer, NSAID-associated duodenal and gastric ulcers or prophylaxis in patients with a history of NSAID-associated duodenal and gastric ulcer, gastro-esophageal reflux disease, long-term management of acid reflux disease, acid-related dyspepsia, severe ulcerative reflux esophagitis, prophylaxis of acid aspiration during general anaesthesia, Zollinger-Ellison syndrome and Helicobacter pylori- induced peptic ulcer.

Dosage and administration

Benign gastric and duodenal ulcer: 20 mg once daily for 4 weeks in duodenal ulceration, 8 weeks in gastric ulceration. In severe recurrent cases, increased to 40 mg daily; maintenance for recurrent duodenal ulcer, 20 mg once daily; prevention of relapse in duodenal ulcer, 10-20 mg daily.

NSAID-associated duodenal or gastric ulcer: 20 mg once daily for 4 weeks, continued for further 4 weeks if not fully healed, 20 mg once daily is used as prophylaxis in patients with a history of NSAID-associated duodenal or gastric ulcer.

Gastro-esophageal reflux disease: 20 mg once daily for 4 weeks, followed by a further 4-8 weeks if not fully healed; 40 mg daily has been given for 8 weeks in reflux esophagitis refractory to other treatment; may be continued at 20 mg daily.

Long-term management of acid reflux disease: 10-20 mg daily.

Acid-related dyspepsia: 10-20 mg once daily for 2-4 weeks.

Prophylaxis of acid aspiration: 40 mg on the preceding evening, then 40 mg 2-6 hours before surgery.

Zollinger-Ellison syndrome: Initially 60 mg once daily; usual range 20-120 mg daily (above 80 mg in 2 divided doses).

Helicobacter pylori eradication regimen in peptic ulcer disease: Eupi 20 is recommended as twice daily in association with antimicrobial agents as detailed below:

Amoxicillin 500 mg and Metronidazole 400 mg both three times a day for one week, or Clarithromycin 500 mg and Metronidazole 400 mg both twice a day for one week, or Amoxicillin 1 g and Clarithromycin 500 mg both twice a day for one week.

Paediatric use in severe ulcerating reflux esophagitis (Child over 1 year): If body weight 10-20 kg, 10-20 mg once daily for 4-12 weeks; if body-weight over 20 kg, 20-40 mg once daily for 4-12 weeks.

Injection:

In patients with gastric ulcer, duodenal ulcer or reflux oesophagitis where

oral medication is inappropriate, Omeprazole IV 40 mg once daily is recommended. In patients with Zollinger-Ellison syndrome, the recommended initial dose of Omeprazole given intravenously is 60 mg daily. Higher daily doses may be required and the dose should be adjusted individually. When doses exceed 60 mg daily, the dose should be divided and given twice daily.

Impaired renal function: Dose adjustment is not required in patients with impaired renal function.

Impaired hepatic function: As bioavailability and half life can increase in patients with impaired hepatic function, the dose requires adjustment with a maximum daily dose of 20 mg.

Elderly: Dose adjustment is not required in elderly.

Children: There is limited experience with Omeprazole IV in children.

Method for use of IV Injection

Eupi IV injection should be given as a slow intravenous injection. The solution for IV injection is obtained by adding 10 ml 0.9% Sodium Chloride BP injection to the vial. After reconstitution, injection should be given slowly over a period of at least 2.5 minutes at a maximum rate of 4 ml per minute. The solution should be used within 4 hours of reconstitution.

Side effects

Omeprazole is generally well tolerated. Nausea, headache, diarrhoea, constipation and flatulence have been stated to be generally mild and transient and not requiring a reduction in dosage.

Precautions

When gastric ulcer is suspected, the possibility of gastric malignancy should be excluded before treatment with Omeprazole is instituted, as treatment may alleviate symptoms and delay diagnosis.

Contraindications

Omeprazole is contraindicated in patients with known hypersensitivity to any of the components of the formulation.

Use in Pregnancy and Lactation

FDA pregnancy category of Omeprazole is C. However, results from three prospective epidemiological studies indicate no adverse effects of Omeprazole on pregnancy or on the health of the foetus or new born child. There is no information available on the passage of Omeprazole into milk or its effects on the neonate. Breast feeding should therefore be discontinued if the use of Omeprazole is considered essential.

Drug interactions

Omeprazole can prolong the elimination of diazepam, warfarin and phenytoin. So, reduction of warfarin or phenytoin dose may be necessary when Omeprazole is added to treatment. There is no evidence of interaction of Omeprazole with theophylline, propranolol or antacids.

Storage

Keep in a cool and dry place, away from light and heat. Keep out of the reach of children.

How Supplied

Eupi 20 Capsule: Box containing 10 x 10 capsules in alu-alu blister pack.

Eupi 40 Capsule: Box containing 3 x 10 capsules in alu-alu blister pack.

Eupi IV Injection: Each combipack contains 1 vial of 40 mg Omeprazole, 1 ampoule of 10 ml sterile 0.9% Sodium Chloride BP injection as solvent & a 10 ml sterile disposable syringe.



* Eupi Injection is manufactured by
The IBI SINA Pharmaceutical Industry Ltd. for
Pharmasia Ltd.

Manufactured by*

Pharmasia Limited

Gojariapara, Bhawal Mirzapur,
Gazipur, Bangladesh

P502606