Opal®

Omeprazole BP

Presentation

Opal® 20 mg capsules: Each capsule contains Omeprazole BP 20 mg as enteric coated pellets.
Opal® 40 mg capsules: Each capsule contains Omeprazole BP 40 mg as enteric coated pellets.
Opal® 40 mg i.v. injection: Each vial contains Omeprazole BP 40 mg (As Omeprazole sodium BP lyophilized sterile powder) and each ampoule contains 10 ml sterile water for injection USP.

Indications

For the treatment of gastro-oesophageal reflux disease, peptic ulcer disease, for the eradication of *Helicobacter pylori* in peptic ulceration (triple therapy), acid related dyspepsia, NSAID associated duodenal or gastric ulcer and gastroduodenal erosions, Zollinger-Ellison Syndrome.

Properties

Opal® (Omeprazole) inhibits secretion of gastric acid by irreversibly blocking the enzyme system of hydrogen/potassium adenosine triphosphatase (H^+/K^+ATPase), the proton pump of the gastric parietal cell oral dosing with Opal®, produces inhibition of gastric acid secretion within 1-2 hours of the first dose. The maximum effect is achieved within 4 days of starting of treatment after which the degree of acid inhibition remains constant.

Pharmacokinetics

Omeprazole is rapidly absorbed. Absorption is not affected by food. Omerazole is acid labile. The absorption of Omeprazole also appears to be dose dependent. Bioavailability of Omeprazole may be increased in elderly patients and in patients with impaired hepatic function. Following absorption Omeprazole is almost completely metabolised in the liver by cytochrome P 450 and rapidly eliminated in the urine. The elimination half life is about 0.5 to 3 hours, its duration of action with regard to inhibition of acid secretion is much longer allowing it to be used in single daily doses. Omeprazole is highly bound (about 95%) to plasma proteins.

Dosage and administration

Capsule: The usual dose of Opal® for the treatment of gastro-oesophageal reflux disease is 20-40 mg daily for 4 to 12 weeks; There after maintenance therapy can be continued with 20 mg daily.
In the management of peptic ulcer disease a single daily dose of 20 mg or in severe cases, 40 mg is given. Treatment is continued for 4 weeks for duodenal ulcer and 8 weeks for gastric ulcer. A dose of 20 mg once daily may be given for maintenance.
For the eradication of *Helicobacter pylori* in peptic ulceration, Opal® (Omeprazole) 40 mg daily in divided doses may be combined with antibacterial in triple therapy.
Doses of 20 mg daily are used in the treatment of ulceration associated with the use of NSAID. A dose of 20 mg daily may also be used for prophylaxis in susceptible patients.
The recommended initial doses for Zollinger-Ellison syndrome is 60 mg (3 caps. of Opal® 20) once daily. The dosage should be adjusted individually and treatment continued as long as clinically indicated. Doses upto 120 mg three times daily have been administered. The majority of patients are effectively controlled by doses in the range 20 to 120 mg daily. With doses above 80 mg daily, the dose should be divided and given twice daily.
For the relief of acid related dyspepsia Omeprazole is given in usual doses of 20 mg daily for 2 to 4 weeks.

Injection: Duodenal ulcer, gastric ulcer and reflux oesophagitis: Patients who cannot be given oral medication can be treated parenterally with 40 mg once daily. The usual treatment period before transfer to oral treatment is 2-3 days. In Zollinger-Ellison syndrome the dose should be adjusted individually. Higher doses and/or several doses daily may be required. Intravenous treatment can be given as an infusion over a period of 20-30 minutes. After reconstitution start the infusion immediately.

Elderly and impaired hepatic function
As bioavailability and half life can be increased in patients with impaired hepatic function as well as elderly, the dose requires adjustment with a maximum daily dose of 20 mg.

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

Method of administration

Opal IV injection 40 mg should be given as a slow intravenous injection. The solution for IV injection is obtained by adding to the vial 10 ml of the solvent provided. (No other solvent should be used). Discoloration may occur if incorrect reconstitution technique is used. For practical information about the reconstitution see the package insert. After reconstitution the 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.

Contraindications

There are no known contraindications to the use of Omeprazole. Before giving Omeprazole to patients with gastric ulcers the possibility of malignancy should be considered since Omeprazole may mask symptoms and delay diagnosis.

Use in pregnancy and lactation

There is no evidence on the safety of Omeprazole in human pregnancy. Animal studies have revealed no teratogenic effect. 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.

Adverse reactions

Opal® is well tolerated and adverse reactions have generally been mild and reversible. The following have been reported as adverse events in clinical trials or reported from routine use but in many cases a relationship to treatment with Omeprazole has not been established. Skin rash, urticaria and pruritus have been reported, usually resolving after discontinuation of treatment, in addition photosensitivity, bollous eruption, erythema, multiform, angioedema and alopecia have been reported in isolated cases. Diarrhhoea and headache have been reported. In the majority of cases the symptoms resolved after discontinuation of therapy.
Other gastrointestinal reaction includes constipation, nausea, vomiting, flatulence and abdominal pain. Stomatitis and candidiasis have been reported as isolated cases. Paraesthesia have been reported Dizziness, lightheadedness and feeling faint have been associated with treatment, but all usually resolve on cessation of therapy.
Also reported are somnolence, insomnia and vertigo. Reversible mental confusion, agitation, depression and hallucinations have occurred predominantly in severely ill patients. Arthritic and myalgic symptoms have been reported and have usually resolved when therapy is stopped.
In isolated cases the following have been reported: blurred vision, taste disturbance, peripheral edema, increased sweating, gynaecomastia, leucopenia, thrombocytopenia, malaise, fever, bronchospasm, encephalopathy in patients with pre-existing severe liver disease, hepatitis with or without jaundice, rarely interstitial nephritis and hepatic failure. Increase in liver enzymes have been observed.

Interactions

Opal® can delay the elimination of diazepam, phenytoin and warfarin. Monitoring of patients receiving warfarin or phenytoin is recommended and a reduction of warfarin or phenytoin dose may be necessary when Omeprazole is added to treatment. There is no evidence of an interaction with theophylline, propranolol, metoprolol, lidocaine, quinidine, amoxycillin or antacids. The absorption of Opal® is not affected by alcohol or food.
Simultaneous treatment with Omeprazole and digoxin in healthy subjects lead to a 10 % increase in the bioavailability of digoxin as a consequence of the increased intragastric pH.

How Supply

Opal® 20 mg capsules: Box containing 10x6 capsules in Alu-Alu blister pack.
Opal® 40 mg capsules: Box containing 8x4 capsules in Alu-Alu blister pack.
Opal® 40 mg i.v. injection: Each combipack contains 1 vial of 40 mg of Omeprazole, 1 ampoule of 10 ml sterile water for injection and 1 sterile disposable syringe 10 ml.

Storage

Store at temperature not exceeding 30 °C in a dry place. Protect from light.

Medicine keep out of reach of children

Healthcare

Manufactured by
Healthcare Pharmaceuticals Ltd.
Rajendrapur, Gazipur, Bangladesh

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