

BENZIM

COMPOSITION:

TABLETS:

Each enteric coated tablet contains: Omeprazole (B.P.)..... 40mg

Product conforms to the Manufacturer's Specifications.

CAPSULES:

Each capsule contains: Omeprazole (Enteric Coated Pellets) B.P.20mg

Product conforms to B.P specification.

INJECTION:

Each vial contains: Omeprazole Sodium Sterile Lyophilized Powder equivalent to Omeprazole (M.S.)....40mg

Product conforms to the Manufacturer's Specifications.

DESCRIPTION:

The active ingredient Omeprazole in Benzim is a substituted benzimidazole, 5-methoxy-2-[[[4-methoxy-3, 5-dimethyl-2-pyridinyl) methyl] sulfinyl]-1H-benzimidazole.

MECHANISM OF ACTION:

Omeprazole belongs to a new class of anti-secretory compound benzimidazole. It 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.

PHARMACOKINETICS:

Absorption: Absorption is rapid, with peak plasma levels of Omeprazole occurring within 0.5 to 3.5 hours. Absolute bioavailability is about 30-40% at doses of 20-40 mg, due in large part to presystemic metabolism. Half-life is 0.5 to 1 hour and the total body clearance is 500-600 mL/min.

Distribution: The apparent volume of distribution in healthy subjects is approximately 0.3L/kg. The plasma protein binding of Omeprazole is about 95%.

Metabolism & Excretion: Omeprazole is almost completely metabolized in the liver. The majority of the dose (about 77%) is eliminated in the urine and the remainder, recoverable in the feces. The total plasma clearance is 0.3 to 0.6L/min. Volume of distribution is slightly decreased, while the plasma half-life of Omeprazole is increased.

INDICATIONS:

Omeprazole (Benzim) is indicated for the treatment of: Gastro-oesophageal reflux disease, Peptic ulcer disease, Treatment and prophylaxis of NSAID-associated ulceration, Zollinger-Ellison syndrome and Prophylaxis of acid aspiration

DOSAGE & ADMINISTRATION OF INJECTION:

Gastro - oesophageal reflux disease, Peptic ulcer disease and Treatment and prophylaxis of NSAID-associated ulceration: Omeprazole (Benzim) I.V. 40mg once daily. Zollinger-Ellison syndrome: Initial dose of Omeprazole (Benzim) I.V. 60mg daily. Dose greater than 60mg should be given twice daily. Prophylaxis of acid aspiration: Omeprazole (Benzim) I.V. 40mg to be completed one hour.



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INSTRUCTIONS OF USE:

Injection: For I.V. injection, reconstitute Omeprazole (Benzim) I.V. with 10ml sterile water for injection to make a 10ml solution containing 4mg/ml Omeprazole approximately. No other solvents for I.V. injection should be used. After reconstitution, Omeprazole (Benzim) I.V. should be given as intravenous injection, slowly over a period of at least 2.5 minutes at a maximum rate of 4ml/min. The reconstituted solution is stable for approximately 8 hours when stored in the original vial in a cool place.

Infusion: For I.V. infusion, reconstitute Omeprazole (Benzim) I.V. with 10ml sterile water for injection to make a 10ml solution containing 4mg/ml Omeprazole approximately. Next add the 10ml reconstituted solution to 90ml of 0.9% w/v of sodium chloride solution for injection or 5% w/v of dextrose solution for injection or 5% w/v of mannitol to make 100ml solution containing 0.4mg/ml of Omeprazole approximately. No other solution should be used for infusion. The reconstituted infusion should be given intravenously over a period of 20-30 minutes.

DOSAGE & ADMINISTRATION OF TABLETS & CAPSULES:

Reflux Oesophagitis: The recommended dosage is Omeprazole (Benzim) 20mg once daily. **Symptomatic Gastro-Oesophageal Reflux Disease (GERD):** The recommended dosage is Omeprazole (Benzim) 20mg once daily. **Zollinger-Ellison Syndrome:** The recommended initial dosage is Omeprazole (Benzim) 60mg daily. When doses exceed Omeprazole (Benzim) 80mg daily, the dose should be divided and given twice daily. **Duodenal Ulcer:** The recommended dosage is Omeprazole (Benzim) 20mg once daily. **Gastric Ulcer:** The recommended dosage is Omeprazole (Benzim) 20mg once daily. **NSAID Associated Gastric Ulcers:** The recommended dosage is Omeprazole (Benzim) 20mg once daily. **Duodenal Ulcers or Gastroduodenal Erosions in patients with or without continued NSAID treatment:** The recommended dosage is Omeprazole (Benzim) 20mg once daily.

CONTRAINDICATIONS:

Omeprazole (Benzim) is contraindicated in patients with known hypersensitivity to any component of the formulation.

WARNINGS:

Omeprazole (Benzim) may be associated with an increased risk of Clostridium difficile associated diarrhea, especially in hospitalized patients.

DRUG-DRUG INTERACTIONS:

The absorption of Ketoconazole and Itraconazole can decrease during treatment with Omeprazole (Benzim)

Omeprazole (Benzim) is metabolized by CYP2C19. The plasma concentrations of drugs like Diazepam, Citalopram, Imipramine, Clomipramine, Phenytoin etc. may be increased and a dose reduction could be needed

ADVERSE DRUG REACTIONS:

Omeprazole (Benzim) is well tolerated and the adverse reactions have generally been mild & reversible.

Common

Central and peripheral nervous system: Headache



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Gastrointestinal: Diarrhoea, Constipation, Abdominal pain, Nausea/Vomiting and Flatulence.

Uncommon

Central and peripheral nervous system: Dizziness, Paraesthesia, Somnolence, Insomnia and Vertigo.

Hepatic: Increased liver enzymes

Skin: Rash and/or pruritis, Urticaria.

Other: Malaise

OVER DOSAGE:

Reports have been received of overdosage with Omeprazole (Benzim) in humans. Doses ranged up to 2400 mg (120 times the usual recommended clinical dose). Symptoms were transient and no serious clinical outcome has been reported when Omeprazole (Benzim) was taken alone. No specific antidote for Omeprazole (Benzim) overdosage is known. Omeprazole (Benzim) is extensively protein bound and is therefore, not readily dialyzable. In the event of overdosage, treatment should be symptomatic and supportive

INSTRUCTIONS:

Store in a cool & dry place below 25°C.

Protect from light, heat and moisture.

Keep out of reach of children.

PRESENTATION:

Tablets: Benzim 40mg tablets are available in a blister pack of 14's.

Capsules: Benzim 20mg capsules are available in a blister pack of 20's.

Injection: Benzim 40mg is a lyophilized powder available as one vial per pack with one ampoule of solvent.



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