Inpro

Omeprazole Capsule & Injection

Composition

Inpro 20 capsule: Each capsule contains Omeprazole USP 20 mg as enteric-coated pellets
Inpro 40 capsule: Each capsule contains Omeprazole USP 40 mg as enteric-coated pellets
Inpro 40 IV Injection: Each vial contains sterile Omeprazole Sodium BP equivalent to Omeprazole 40 mg

Description

Inpro (Omeprazole), a substituted benzimidazole, is an inhibitor of gastric acid secretion from the parietal cell. The effect is dose-dependent. **Mode of action:** Omeprazole inhibits secretion of gastric acid by blocking the hydrogen-potassium-adenosine triphosphatase enzyme system, the so-called 'proton pump' of the gastric parietal cell.

Indications

Inpro (Omeprazole) is indicated for the treartment of following conditions: Gastric ulcers, Duodenal ulcers, NSAID -induced gastric upsets, Helicobacter pylori eradication, Erosive & non-erosive reflux esophagitis, Gastro esophageal reflux disease, (GERD), Prophylaxis of acid aspirations, Acid related dyspepsia, Zollinger-Ellison syndrome.

Dosage and Administrations: Capsule:

For adults: For the treatment of Gastric ulcer: 40 mg once a day for 4 - 8 weeks. **For the treatment of Duodenal ulcer:** 20 mg once daily. Most heal within 4 weeks. **NSAID -induced gastric upsets:** 20 mg once a day and **prophylaxis:** 20 mg once a day. **Helicobacter pylori eradication:** 20 mg twice daily plus clarithromycin 500mg plus metronidazole 400 mg for 10 days. **Erosive esophagitis:** Maintenance therapy with 20 mg daily. **Gastro esophageal reflux disease, GERD:** 20 mg once daily. **Prophylaxis of acid aspirations:** 40 mg on the preceeding evening then 40 mg 2 to 6 hours before surgery. **Acid related dyspepsia:** Maintenance therapy with 20 mg daily. **Zollinger-Ellison syndrome:** The starting dose is 60 mg once a day.

For paediatric patients: For the treatment of GERD or other acid-related disorders, the recommended dose for paediatric patients 2 years of age and older is as follows:

Patient weight	Omeprazole dose
< 20 KG	10 mg
⩾ 20 KG	20 mg

Inpro capsule should be taken before eating. It should not be opened, chewed or crushed and should be swallowed whole.

Inpro 40 mg IV injection:

In patients with duodenal ulcer, gastric ulcer or reflux esophagitis: 40 mg once daily

In patients with Zollinger-Ellison syndrome: initial dose 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 not needed.

Impaired hepatic function: As plasma half life of omeprazole is increased in patients with impaired hepatic function, a daily dose of 10 - 20 mg may be sufficient. **Elderly:** Dose adjustment not needed. **Children 1 month** - 12 years: initially 500 mcg/kg (max 20 mg) once daily, increased to 2 mg/kg (max. 40 mg) once daily. **Child 12 - 18 years:** 40 mg once daily

Method of administration:

Inpro 40 mg IV injection should be given as slow intravenous injection. The solution for IV injection is obtained by adding to the vial 10 ml of the solvent provided. 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 hour of reconstitution when stored in original vial in a cool place. The reconstituted solution should not be used if it contains visible particulate matter.

Infusion:

For IV infusion reconstitute one sterile single dose vial of Inpro IV injection with the provided 10 ml solvent in ampoule to make 10 ml solution containing 4 mg/ml of omeprazole approximately. Subsequently add 10 ml of reconstituted solution containing 4 mg/ml of omeprazole approximately, to 90 ml 0.9% sodium chloride solution to make 100 ml solution of 0.4 mg/ml of

omeprazole approximately. The resultant infusion should be given intravenously over a period of 20 - 30 minutes. Chemical and physical in-use stability has been demonstated for 12 h after reconstitution with saline or for 6 h after reconstitution with 5% Dextrose. From a microbiological point of view, the product should be used immediately. Any unused portion should be discarded.

Contra-indications:

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.

Precaution:

Symptomatic response to therapy with Inpro (omeprazole) does not preclude the presence of gastric malignancy.

Use in Pregnancy and Lactation:

There are no adequate & well controlled studies in pregnant women. 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.

Side- Eeffects:

Inpro is well tolerated. Nausea, diarrhoea, abdominal colic, paresthesia, dizziness and headache have been stated to be generally mild and transient and not requiring a reduction in dosage.

Drug interaction:

Omeprazole can delay the elimination of diazepam, phenyntoin and warfarin. Reduction of warfarin or phenyntoin dose may be necessary when omeprazole is added to treatment. There is no evidence of an interaction with theophylline, propranolol or antacids. 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.

Pharmaceutical Precaution:

Store at room temperature (below 30^{o} C). Protect from light and humidity.

Commercial Pack:

Inpro 20 capsule: Each box contains 10 alu-alu blister pack of 10 capsules.

Inpro 40 capsule: Each box contains 6 alu-alu blister pack of 10 capsules.

Inpro 40 mg IV injection: Each combipack contains 1 vial of 40 mg omeprazole and one ampoule of 10 ml sterile 0.9% sodium chloride BP injection or 10 ml water for injection BP as solvent.

Inpro 40 mg IV injection is Manufactured by Popular Pharmaceuticals Ltd. for Biopharma Ltd.

Manufactured by
BIOPHARMA
LIMITED
A-116, BSCIC Industrial Estate
Tongi, Gazipur, Bangladesh

For further query on the use of this medicine, consult to a registered Doctor or Pharmacist.