PPI

Capsule
IV Injection

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Omeprazole

COMPOSITION

PPI 20: Each capsule contains Omeprazole BP 20 mg as enteric coated pellets.
PPI 40: Each capsule contains Omeprazole BP 40 mg as enteric coated pellets.
PPI IV: Each vial contains lyophilized powder of Omeprazole Sodium BP equivalent to 40 mg Omeprazole.

DESCRIPTION

PPI (Omeprazole), the substituted benzimidazole, is an inhibitor of gastric acid secretion. Omeprazole inhibits the secretion of gastric acid by blocking the H+/K+ATPase (hydrogen-potassium-adenosine triphosphatase) enzyme system, the so-called "proton pump" of the gastric parietal cell.

INDICATIONS

Benign gastric and duodenal ulcer, heart burn, NSAID-associated complications, peptic ulcer associated with Helicobacter pylori, gastro-oesophageal reflux disease, Zollinger-Ellison syndrome, prevention of acid aspiration syndrome, acid related dyspepsia and other hyper acidic complications.

DOSAGE AND ADMINISTRATION

Adults

Capsule:

PPI (Omeprazole) should be taken before meal.

Benign gastric and duodenal ulcers: 20 mg once daily for 4 weeks in duodenal ulceration or 8 weeks in gastric ulceration; in severe or recurrent cases increase to 40 mg daily; maintenance for recurrent duodenal ulcer, 20 mg once daily; prevention of relapse in duodenal ulcer : 10 to 20 mg once daily if symptoms return.

Heart burn : 20 mg once daily for 14 days.

NSAID-associated complications: NSAID-associated duodenal or gastric ulcer & gastroduodenal erosions, 20 mg once daily for 4 weeks, followed by a further 4 weeks if not fully healed; prophylaxis in patients with a history of NSAID-associated duodenal or gastric ulcers, gastroduodenal lesions, or dyspeptic symptoms who require continued NSAID treatment, 20 mg once daily.

Peptic ulcer associated with Helicobacter pylori:

Regimen	Duration
Omeprazole (**PPI**) 20 mg twice daily. Amoxicillin (**MOXILIN**) 1 g twice daily. Clarithromycin (**CLARICIN**) 500 mg twice daily.	01-02 weeks
Omeprazole (**PPI**) 20 mg twice daily. Clarithromycin (**CLARICIN**) 500 mg twice daily. Metronidazole (**DIROZYL**) 400 mg twice daily.	01 week
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Gastro-oesophageal reflux disease: 20 mg once daily for 4 weeks, followed by a further 4-8 weeks if not fully healed; 40 mg once daily has been given for 8 weeks in gastro-oesophageal reflux disease refractory to other treatment; may be continued at 20 mg once daily.
Maintenance therapy : 10-20 mg once daily.

Zollinger-Ellison syndrome: Initially 60 mg (40+20 mg) once daily; usual range 20-120 mg daily (above 80 mg in 2 divided doses).

Gastric acid reduction during general anaesthesia (prophylaxis of acid aspiration): 40 mg on the preceding evening, then 40 mg 2-6 hours before surgery.

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

Injection :

Benign gastric ulcer, duodenal ulcer and gastro-oesophageal reflux disease, 40 mg once daily until oral administration is possible, prophylaxis of acid aspiration, 40 mg completed 1 hour before surgery.
In patients with Zollinger-Ellison syndrome the recommended initial dose 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.

Method of Administration

Injection: The solution for IV injection is prepared by 10 ml of WFI (provided) adding to the vial. After reconstitution the injection should be given over 5 minutes or at least by 2.5 minutes at a maximum rate of 4 ml per minute. The solution should be used within 4 hours 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: PPI IV infusion 40 mg should be given as an intravenous infusion (over a period of 20-30 minutes or more). The contents of one vial must be dissolved in 100 ml saline for infusion or 100 ml 5% dextrose solution for infusion. The solution should be used within 12 hours when omeprazole is dissolved in saline and within 6 hours when dissolved in 5% dextrose solution. The constituted solution should not be mixed or co-administered in the same infusion set with any other drug.

Use in children

Capsule :

Child over 2 years : Severe ulcerating reflux oesophagitis, 0.7-1.4 mg/kg daily for 4-12 weeks; maximum 40 mg daily (to be initiated by hospital physician under close supervision).

Injection :

There is limited experience of use in children.

Elderly

Dose adjustment is not required in the elderly.
Impaired renal or hepatic function : Dose adjustment is not required in renal impairment. Patients with severe liver disease should not require more than 20 mg Omeprazole daily.
OR AS DIRECTED BY THE PHYSICIAN.

SIDE EFFECTS

PPI (Omeprazole) is well tolerated. But nausea, diarrhoea, constipation, flatulence, abdominal pain, dizziness, headache, skin rashes may occur rarely.

CONTRAINDICATIONS

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

PRECAUTION

Symptomatic response to therapy with Omeprazole does not preclude the presence of gastric malignancy. When gastric ulcer is suspected, the possibility of malignancy should be excluded before treatment with Omeprazole is instituted as treatment may alleviate symptoms and delay diagnosis.

USE IN PREGNANCY AND LACTATION

There are no adequate or well-controlled studies in pregnant women. Use during pregnancy only if the potential benefit justifies the risk to the fetus. Omeprazole is excreted in breast milk. So a decision should be made whether to discontinue nursing or the drug, taking into account the importance of the drug to the mother.

DRUG INTERACTIONS

PPI (Omeprazole) can delay the elimination of diazepam, phenytoin and warfarin. 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 or antacids.

OVERDOSE

Oral doses up to 400 mg have not resulted in severe symptoms. Omeprazole IV doses of up to 270 mg on a single day and up to 650 mg over a three-day period have been given in clinical trials without any dose-related adverse reactions.

SUPPLY

PPI 20: Each box contains 10 X 14 capsules in alu-alu blister strips.
PPI 40: Each box contains 4 X 10 capsules in alu-alu blister strips.
PPI IV: Each combipack contains 1 vial of 40 mg lyophilized Omeprazole and 1 ampoule of 10 ml Water for Injection with a 10 ml sterile disposable syringe.

Store in a cool & dry place, protected from light.
Keep all medicines out of reach of children.

**** Further information is available on request.***

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Manufactured by:
The ACME Laboratories Ltd.
Dhamrai, Dhaka, Bangladesh
ISO 9001: 2015 Certified Company