Rx

OMEPRAZOLE

SIDPRAZOLE
40mg Lyophilized Powder For IV Injection
PROTON PUMP INHIBITOR

FORMULATION:
Each vial contains:
Omeprazole (as Sodium) 40mg

PRODUCT DESCRIPTION:
A white or slightly white, crystalline crumbly cake or powder.

INDICATIONS: It is used in conditions where inhibitors of gastric acid secretion may be beneficial, including aspiration syndromes, dyspepsia, gastroesophageal reflux disease and the Zollinger-Ellison syndrome.

PHARMACOKINETICS: Omeprazole is rapidly but variably absorbed after oral doses. Absorption is not affected by food. Omeprazole is acid-labile and pharmacokinetics may vary between the various formulations developed to improve oral bioavailability. The absorption of omeprazole also appears to be dose-dependent; increasing the dosage above 40 mg has been reported to increase the plasma concentrations in a non-linear fashion because of saturable first-pass hepatic metabolism. In addition, absorption is higher after long-term use. Bioavailability of omeprazole may be increased in elderly patients, in some ethnic groups such as Chinese, and in patients with hepatic impairment, but is not markedly affected in patients with renal impairment. Following absorption, omeprazole is almost completely metabolised in the liver, primarily by the Cytochrome P450 isoenzyme CYP2C19 to form hydroxy-omeprazole, and to a small extent by CYP3A to form omeprazole sulfone. The metabolites are inactive, and are excreted mostly in the urine and to a lesser extent in bile. The elimination half-life from plasma is reported to be about 0.5 to 3 hours. Omeprazole is about 95% bound to plasma proteins.

DOSAGE & ADMINISTRATION: Omeprazole is a proton pump inhibitor. 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. It is used in conditions where inhibition of gastric acid secretion may be beneficial, including aspiration syndromes dyspepsia, gastro-oesophageal reflux disease, peptic ulcer disease, and the Zollinger-Ellison syndrome. Esomeprazole, an isomer of omeprazole, is also used. Omeprazole may be given by mouth as the base or magnesium salt, or intravenously as the sodium salt. Doses are expressed in terms of the base. Omeprazole magnesium 10.32 mg and omeprazole sodium 10.64 mg are each equivalent to about 10 mg of omeprazole. For the relief of acid-related **dyspepsia,** omeprazole is given in usual doses of 10 or 20 mg daily by mouth for 2 to 4 weeks. The usual dose for the treatment of **gastro-oesophageal reflux disease** is 20 mg by mouth once daily for 4 weeks, followed by a further 4 to 8 weeks if not fully healed. In refractory oesophagitis, a dose of 40 mg daily may be used. Maintenance therapy after healing of oesophagitis is 20 mg once daily, and for acid reflux is 10 mg daily. In children over 1 year of age, licensed UK oral doses for treatment are 10 mg daily in those weighing 10 to 20 kg, and 20 mg daily in those weighing over 20 kg. These doses may be doubled if necessary. The BNFC recommends a dose of 700 micrograms/kg daily in children 1 month to 2 years of age, increased if necessary up to 3 mg/kg daily, or 20 mg daily, whichever is less. Similar initial doses are suggested in neonates. In the management of **peptic ulcer disease** a single daily dose of 20 mg by mouth, or 40 mg in severe cases, is given. Treatment is continued for 4 weeks for duodenal ulcer and 8 weeks for gastric ulcer. Where appropriate, a dose of 10 to 20 mg once daily may be given for maintenance. For the eradication of *Helicobacter pylori* in peptic ulceration, omeprazole may be combined with antibacterials in dual or triple therapy. Effective **triple therapy** regimens include omeprazole 20 mg twice daily combined with: amoxicillin 500 mg and metronidazole 400 mg, both three times daily; clarithromycin 500 mg and metronidazole 400 mg (or tinidazole 500 mg) both twice daily; or with amoxicillin 1 g and clarithromycin 500 mg both twice daily. These regimens are given for 1 week. **Dual therapy** regimens such as omeprazole 40 mg daily with either amoxicillin 750 mg to 1 g twice daily or clarithromycin 500 mg three times daily, are less effective and must be given for 2 weeks. Omeprazole alone may be continued for a further 4 to 8 weeks. Doses of 20 mg daily are used in the treatment of **NSAID-associated ulceration**; a dose of 20 mg daily may also be used for prophylaxis in patients with a history of gastroduodenal lesions who require continued NSAID treatment. The initial recommended dosage for patients with the **Zollinger-Ellison syndrome** is 60 mg by mouth once daily, adjusted as required. The majority of patients are effectively controlled by doses in the range 20 to 120 mg daily, but doses up to 120 mg three times daily have been used. Daily doses above 80 mg should be given as divided doses (usually 2). Omeprazole is also used for the prophylaxis of **acid aspiration** during general anaesthesia, in a dose of 40 mg in the evening before surgery and a further 40 mg two to six hours before the procedure. The dose of omeprazole may need to be reduced in patients with hepatic impairment. PARENTERAL DOSAGE. In patients who are unsuited to receive oral therapy omeprazole sodium may be given on a short-term basis by intravenous infusion, in a usual dose equivalent to 40 mg of the base over a period of 20 to 30 minutes. It may also be given by slow intravenous injection. Higher intravenous doses have been given to patients with Zollinger-Ellison syndrome.

OVERDOSAGE: There have been reports of overdosage with omeprazole in humans. Doses ranged up to 2400 mg (120 times the usual recommended clinical dose). Manifestations were variable but included: Confusion, drowsiness, blurred vision, tachycardia, nausea, vomiting, diaphoresis, flushing, headache, dry mouth and other adverse reactions similar to those seen in normal clinical experience (see Adverse Reactions). Symptoms were transient, and no serious clinical outcome has been reported when omeprazole was taken alone. No specific antidote for omeprazole overdosage is known. Omeprazole is extensively protein bound and is therefore, not readily dialyzable. In the event of overdosage, treatment should be symptomatic and supportive.

CONTRAINDICATIONS: Known hypersensitivity to any components of SIDPRAZOLE 40 mg Lyophilized powder for IV injection.

REPORTING OF SUSPECTED ADVERSE REACTIONS: To allow continued monitoring of the benefit/risk balance of the medicinal product, reporting of suspected adverse reactions is necessary. Healthcare professionals are encouraged to report any suspected adverse reaction/s directly to the importer/distributor and/or to FDA: www.fda.gov.ph. Patients are advised to seek immediate medical attention at the first sign/s of adverse reactions.

PRECAUTIONS: General: Symptomatic response to therapy with omeprazole does not preclude the presence of gastric malignancy. Atrophic gastritis has been noted occasionally in gastric courpus biopsies from patients treated long-term with omeprazole. Information for Patients: Omeprazole delayed-release capsules should be taken before eating. Patients should be cautioned that the omeprazole delayed-release capsules should not be opened, chewed or crushed, and should be swallowed whole.

DRUG INTERACTIONS: Other: Omeprazole can prolong the elimination of diazepam. Warfarin and phenytoin, drugs that are metabolized by oxidation in the liver. Although in normal subjects no interaction with theophylline or propranolol was found. There have been clinical reports of interaction with other drugs metabolized via the Cytochrome P-450 system (e.g., cyclosporine, disulfiram, benzodiazepines). Patients should be monitored to determine if it is necessary to adjust the dosage of these drugs when taken concomitantly with omeprazole. Because of its profound and long-lasting inhibition of gastric acid secretion, it is theoretically possible that omeprazole may interfere with absorption of drugs where gastric pH is an important determinant of their bioavailability (e.g., ketoconazole, ampicillin esters and iron salts). In the clinical trials, antacids were used concomitantly with the administration of omeprazole.

CAUTION: Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

STORAGE: Store at temperatures not exceeding 30°C. Keep out of reach of children.

Availability: In USP type I glass vial (Box of 1's)

Manufactured by:
Harbin Pharmaceutical Group Bioengineering Co.,Ltd.
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