oedema, malaise, hyponatraemia, hypomagnesaemia, blood disorders (including agranulocytosis, leucopenia, and thrombocytopenia), gynaecomastia, impotence, and interstitial nephritis. Cardiovascular effects may occur, including angina, tachycardia or bradycardia. Pancreatitis (sometimes fatal) has been reported, as have tinnitus, urinary disorders, and eye disorders.

Proton pump inhibitors may increase the risk of gastrointestinal infections because of their acid suppressive effects. The absorption of some vitamins and minerals may be reduced.

Early toxicological studies identified carcinoid –like tumours of the gastric mucosa in rats given very high doses of omeprazole over long periods.

DOSES AND ADMINISTRATION

Omeprazole is a proton pump inhibitor. It suppresses secretion of gastric acid by inhibiting 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.

- Prophylaxis of acid aspiration: 40 mg by IV injection or infusion completed 1 hour before surgery.
- Benign gastric ulcer, duodenal ulcer and gastro-oesophageal reflux: 40mg by IV injection or infusion once daily, until oral administration is possible (recommended duration of treatment is up to 5 days).
- Zollinger--Ellison syndrome: 60mg by IV injection or infusion twice daily.
- Gastrointestinal haemorrhage following successful haemostasis of bleeding peptic ulcers (unlicensed): 80mg by IV injection followed by a continuous IV infusion of 8 mg/hour for 72 hours.1
- Dose in hepatic impairment: 20mg daily by IV injection or infusion may be sufficient.

Omeprazole sodium is a proton pump inhibitor (PPI).

It is used IV when the oral route is temporarily unavailable, to treat conditions where inhibition of gastric acid secretion may be beneficial: treatment and prevention of gastric and duodenal ulcers,gastro-oesophageal reflux disease (GORD) and Zollinger--Ellison syndrome.It is also used (unlicensed) for acute GI bleeding and to prevent re-bleeding following therapeuticendoscopy for acute bleeding gastric or duodenal ulcers.

There are two preparations available: IV injection and IV infusion. The IV injection preparation is accompanied by 10mL special solvent containing macrogol 400, citric acid and WFI.

Doses are expressed in terms of omeprazole:

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 in 100 ml of sodium chloride 0.9 % or glucose 5 %. It may also be given by slow intravenous injection. Higher intravenous doses have been given to patients with Zollinger-Ellison syndrome, with a usual initial dose of 60 mg daily.

Although unlicensed in the UK for major peptic bleeding after endoscopy, the BNF suggests that omeprazole 80 mg can be infused intravenously over 40 to 60 minutes, followed by a continuous infusion of 8 mg/hour for 72 hours; treatment can then be continued orally.

PREPARATIONS & ADMINISTRATION:

Intermittent intravenous infusion (using the preparation for IV infusion)

Preparation and administration

1. Add approximately 10 ml NaCl 0.9%, Water for Injection or Glucose 5% from a 100-mL bag to each omeprazole vial.
2. Mix thoroughly to dissolve and transfer the required dose to the infusion bag.
3. Repeat steps 1--2 to ensure the full dose is transferred or use a double-ended transfer needle device for the whole process.
4. The solution should be clear and colourless. Inspect visually for particulate matter or discoloration prior to administration and discard if present.
5. Give by IV infusion over 20--30 minutes.

Intravenous injection

Preparation and administration

1. Withdraw 10mL solvent (WFI) from the ampoule and add approximately 5mL to the omeprazole vial.
2. Immediately withdraw as much air as possible from the vial back into the syringe in order to reduce positive pressure and add the remaining solvent into the vial.
3. Rotate and shake the vial to ensure all the powder has dissolved.

PREGNANCY & LACTATION

Results from three prospective epidemiological studies (more than 1000 exposed outcomes) indicate no adverse events of omeprazole on pregnancy or on the health of the foetus/newborn child. Omeprazole can be used during pregnancy.

Omeprazole is excreted in breast milk but is not likely to influence the child when therapeutic doses are used.

OVERDOSAGE

There is limited information available on the effects of overdoses of omeprazole in humans. In the literature, doses of up to 560 mg have been described, and occasional reports have been received when single oral doses have reached up to 2,400 mg omeprazole (120 times the usual recommended clinical dose). Nausea, vomiting, dizziness, abdominal pain, diarrhoea and headache have been reported. Also apathy, depression and confusion have been described in single cases.

The symptoms described have been transient, and no serious outcome has been reported. The rate of elimination was unchanged (first order kinetics) with increased doses. Treatment, if needed, is symptomatic.

Intravenous 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.

PRECAUTIONS

Before giving omeprazole or other proton pump inhibitors to patients with gastric ulcers the possibility of malignancy should be excluded since these drugs may mask symptoms and delay diagnosis. Omeprazole and other proton pump inhibitors should be used with caution in hepatic impairment and dose adjustment may be required.

Storage: -Store below 25 °C protect from light.

Improper Storage may deteriorate the product

Medicine: - Keep out of reach of children.

Presentation: -Each pack contain Omeprazole for Injection (40 mg)in a vial. And Sterile Water for injection 10 ml & 20 inner carton pack in a outer .

Manufactured by:

AMERICAN REMEDIES
Care & Cure with Research

American Remedies Healthcare Pvt. Ltd.
(An ISO 9001-2015 Certified Company)
ICO: American Remedies LLC, DE, USA

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For the use only of a Registered Medical Practitioner of a Hospital or a Laboratory

Rx Omeprazole For Injection 40 mg

AMERICAN

OMEECAN 40
Injection

For IV use only

Composition:-

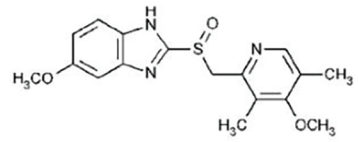
Each Vial Contains:-

Omeprazole Sodium (Sterile)	IP
Eq. to Omeprazole	40 mg
(Lyophilized)	

DESCRIPTION

Omeprazole For Injection, contain Omeprazole Sodium which is a proton pump inhibitor. It is a substituted 5-methoxy-2[[(4-methoxy-3,5 dimithyl-pyridine-2yl)methyl] sulfinyl]-1Hbenzimidazole,sodium salt. It has an empirical formula of $C_{17}H_{19}N_3NaO_3S$ and a molecular weight of 345.4.

The stability of Omeprazole Sodium is a function of pH; it is rapidly degraded in acid media, and is more stable under alkaline conditions. The structural figure is:



Omeprazole Sodium

PHARMACOLOGY

PHARMACOKINETICS

Omeprazole is rapidly but variably absorbed after oral doses. Absorption is not significantly affected by food. Omeprazole is acid-labile and the pharmacokinetics of the various formulations developed to improve oral bioavailability may vary. The absorption of omeprazole also appears to be dosedependent; 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, bioavailability is higher after long termuse.

Bioavailability of omeprazole may be increased in elderly patients, in some ethnic groups such as Chinese, and in patients with hepatic in impairment, but is not markedly affected in patients with renal impairment.

On absorption, omeprazole is almost completely metabolised in the liver, mainly by the cytochrome P4 SO Isoenzyme CYP2 C 1 9 to form hydroxy-omeprazole, and to a small extent by CYP3A4 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 % in bound to plasma proteins.

METABOLISM

The major enzyme involved in omeprazole metabolism is cytochrome P4SO isoenzyme CYP2Cl9. This enzyme is polymorphically expressed, and individuals who are deficient in the enzyme are poor metabolisers of omeprazole. This occurs in about 3 % of Caucasians and 15% of Chinese, Japanese, and Koreans. These individuals have markedly higher plasma concentrations of omeprazole, and they may require dosage adjustment. Some omeprazole is metabolised by CYP3A4, and some by CYP2D6 to form desmethylomeprazole.

DRUG INTERACTIONS

Omeprazole and other proton pump inhibitors are metabolised by the cytochrome P450 system, mainly by isoenzyme CYP2 C 19, and to a smaller extent by CYP3A4. Inhibitors or inducers of these isoenzymes may affect exposure to omeprazole and other proton pump inhibitors. In turn, proton pump inhibitors may alter the metabolism of some drugs metabolised by these enzymes. Omeprazole also inhibits CYP2C 1 9 and may prolong the elimination of cilostazol, diazepam, phenytoin, and warfarin. Omeprazole and other proton pump inhibitors can affect the absorption of drugs such as dasatinib, erlotinib, posaconazole, ketoconazole, and it raconazole, whose absorption is dependent on an acid gastric pH. With voriconazole, the plasma concentration of both drugs may be increased. Other proton pump inhibitors may he similarly affected by voriconazole. Omeprazole and other proton pump inhibitors should not be used with atazanavir or nelfinavir, as it substantially reduces exposure to the HIV –protease inhibitor.

The decrease in gastric activity with proton pump inhibitors may give false positive results in diagnostic investigations for neuroendocrine tumours and treatment should be stopped before such investigations.

Omeprazole is mainly metabolised by the cytochrome P 450 is oenzyme CYP2C19 and therefore may interact with diazepam. Some metabolism of phenytoin, to lbutamide, and the Renantiomer of warfarin also takes place by CYP2 C19, but the effects seen have been minor 1 althoughsome induction of CYP 1A2, which metabolises caffeine and theophylline, has been reported this does not appear to be clinically significant.' While some consider the effect of omeprazole on CYP3A4 activity to be insignificant,' others have noted increasing evidence that competitive inhibition of intestinal CYP3A4 by omeprazole may affect the first-pass metabolism of several drugs. A review concluded that, while omeprazole and possibly esomeprazole have a considerable potential for drug interactions, lansoprazole, pantoprazole and rabeprazole are associated with a lower incidence of drug interactions. For a study in vitro suggesting that omeprazole affected CYP3A4 metabolism of tacrolimus, For more on the effect of proton pump inhibitors on tacrolimus, Proton pump inhibitors, including omeprazole, may also affect exposure to my cphenolate, For a study suggesting that omeprazole reduces the absorption of cyanocobalamin and vitamin C, see Malabsorption, and for its effect on calcium absorption. For reference to possible interactions between methotrexate and omeprazole,

ADVERSE REACTIONS

Proton pump inhibitors are generally well tolerated, and adverse effects are relatively infrequent. The adverse effects reported most often with omeprazole and other proton pump inhibitors have been headache, gastrointestinal disturbances, and rash; they have sometimes been severe enough to require stopping treatment.

Other effects include pruritus, dizziness, fatigue, cough, back or abdominal pain, arthralgia and myalgia, urticaria, and dry mouth. Isolated cases of photosensitivity, bullous eruption, erythema multiforme, and Stevens-Johnson syndrome have occurred; toxic epidermal necrolysis has sometimes been fatal. Systemic hypersensitivity reactions, including fever, bronchospasm, angioedema, and anaphylaxis have been reported. Effects on the CNS include occasional insomnia, somnolence, aggression, and vertigo; reversible confusional states, agitation, depression, and hallucinations have occurred in severely ill patients. Raised liver enzymes, and isolated cases of hepatitis, jaundice, and hepatic encephalopathy have been reported; fatalities have occurred from hepatic failure or necrosis.

Other adverse effects reported rarely include gastrointestinal (including oesophageal) candidiasis, muscular weakness, paraesthesia, blurred vision, alopecia, stomatitis, increased sweating, taste disturbances, peripheral