OMEPRAZOLE

RAMEZOLE Rx

40 mg Lyophilized Powder for Injection (I.V.)
PROTON PUMP INHIBITOR

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

DESCRIPTION:
Omeprazole is a proton pump inhibitor. It suppresses of gastric acid by inhibiting the enzyme system of hydrogen/potassium adenosine triphosphatase (H^+/K^+ ATpase), the "proton pump" of the gastric parietal cell. An almost white lyophilized cake.

PHARMACOKINETICS:
Omeprazole is rapidly but variably 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 appear to be dose dependent; increasing the dosage above 40mg has been reported to increase the plasma concentration in a non-liner fashion because of saturable first-pass hepatic metabolism. In addition, bioavailability is higher after long-term use. On absorption, omeprazole is almost completely metabolised in liver, primarily by the cytochrome P450 isoenzyme CYP2C19 for form hydroxyl-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 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.

METABOLISM:
The major enzyme involved in omeprazole metabolism is cytochrome P450 isoenzyme CYP2C19. This enzyme is polymorphically expressed, and individuals who are deficient in the enzyme are poor metabolisers of omeprazole. This occurs in about 3% Caucasians and 15% of Chinese, Japanese, and Koreans. These individual have markedly higher plasma concentration of omeprazole, and they may require dosage adjustment. Some omeprazole and they may require dosage adjustment. Some omeprazole is metabolized by VYP3A4, and by CYP2D6 to form desmethylomenprazole.

INDICATIONS:
Used in conditions where inhibition of gastric acid secretion may be beneficial, including aspiration syndromes, dyspepsia, gastroesophageal reflux disease, peptic ulcer disease, and the Zollinger-Ellison syndrome.

DOSAGE AND ADMINISTRATION:
Patients who are unsuited to receive oral therapy omeprazole sodium may be on a short-term basis by intravenous infusion of 20 to 30 minutes in 100mL of sodium chloride. It may be also given by slow intravenous injection. Higher intravenous injection over has been given to patients with Zollinger Ellison Syndrome.

OVERDOSE AND TREATMENT:
In the case of overdose/aggravated symptoms, appropriate monitoring and management of the patient should be implemented.

DIRECTION FOR RECONSTITUTION:
The powder should be reconstituted with 10mL of 0.9% sodium chloride injection. Withdraw 10mL of the reconstituted solution and administered as slow intravenous injection over no less than 3 minutes or by intravenous infusion over 10 to 30 minutes. The reconstituted solution should be stored at room temperature not exceeding 30°C and should be administered within 4 hours after reconstitution. No refrigeration is required.

PRECAUTIONS:
Before giving omeprazole or other Proton Pump Inhibitors (PPIs) to patients with gastric ulcers, the possibility of malignancy should be excluded since these drug may mask symptoms and delay diagnosis. Omeprazole and other PPIs should be used with caution in hepatic impairment and dose adjustment may be required.

CONTRAINDICATIONS:
Omeprazole is contraindicated in patients with known hypersensitivity to substituted benzimidazoles or to any component of the formulation.

Hypersensitivity reactions may include anaphylaxis, anaphylactic shock, angioedema, bronchospasm, interstitial nephritis, and urticaria.

DRUG INTERACTIONS:
Omeprazole and other proton pump inhibitors are metabolised by the cytochrome P450 system, primarily by isoenzyme CYP2C19, 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 may prolong the elimination of diazepam, phenytoin, and warfarin. Omeprazole and other proton pump inhibitors can reduce the absorption of drugs such as dasatinib, ketoconazole, and itraconazole, 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 be similarly affected by voriconazole. Omeprazole and other proton pump inhibitors should not be used with atazanavir, as it substantially reduces exposure to atazanavir.

ADVERSE EFFECTS:
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, diarrhoea, and skin rashes; they have sometimes been severe enough to require stopping treatment. Other effects include pruritus, dizziness, fatigue, constipation, nausea and vomiting, flatulence, abdominal pain, arthralgia and myalgia, urticaria, and dry mouth. Isolated cases of photosensitivity, bullous eruption, erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis have occurred. Hypersensitivity reactions, including fever, bronchospasm, angioedema, and anaphylaxis have been reported. Effects on the CNS include occasional insomnia, somnolence, and vertigo; reversible confusional states, agitation, depression, and hallucinations have occurred in severely ill patients. Raised liver enzymes, and isolated cases of hepatitis, jaundice, hepatic failure, and hepatic encephalopathy, have been reported. Other adverse effects reported rarely include paraesthesia, blurred vision, alopecia, stomatitis, increased sweating, taste disturbances, peripheral oedema, malaise, hyponatraemia, blood disorders (including agranulocytosis, leucopenia, and thrombocytopenia), gynaecomastia, impotence, and interstitial nephritis. Proton pump inhibitors may increase the risk of gastrointestinal infections because of their acid suppressive effects.

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

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

STORAGE CONDITION:
Store at temperatures not exceeding 30°C.

AVAILABILITY:
10 mL USP type I Clear and Colorless Glass Vial + 10 mL 0.9% Sodium Chloride as diluent in USP Type I clear and Colorless Glass Ampoule (Box of 1's).

FDA Registration No.	: DRP-5041-01
Date of Renewal of Authorization	: 14 SEP 2020
Date of Revision of Package Insert	: 05 OCT 2020

Manufactured by :
ARISTOPHARMA LTD.
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Imported by:
SAHAR INTERNATIONAL TRADING INC.
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Parañaque City.

Distributed by:
AMSON PHARMACEUTICALS
356 Aguirre Ave, Phase III, BF Homes
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