OMEPRAZOLE

GASTREC™ 20 & 40

Delayed Release Capsule

PROTON PUMP INHIBITOR

FORMULATION:
Each capsule contains:
Omeprazole ..... 20 mg & 40 mg

ACTIONS:
Pharmacology: Omeprazole belongs under a class of drugs called proton pump inhibitors. Omeprazole blocks or inhibits gastric acid secretions. It reduces gastric acid secretion by inhibiting the enzyme system of hydrogen - potassium adenosine triphosphate, which is regarded as the acid proton pump of the gastric parietal cells. Also called H+ / K+ – Atpase, the enzyme is responsible for the exchange of hydrogen and potassium ions during the formation of hydrochloric acid.

PHARMACOKINETICS:
Omeprazole is rapidly but variably absorbed following oral administration. Absorption is not affected by food. Omeprazole is acid-labile. The absorption of omeprazole 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 administration. Bioavailability of omeprazole may be increased in elderly patients, in some ethnic groups such as Chinese, and in patients with impaired hepatic function, but is not markedly affected in patients with renal impairment. Following absorption, omeprazole is almost completely metabolized in the liver, primarily by the cytochrome P450 isoenzyme CYP2C19 to form hydroxyomeprazole, 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 the bile. The elimination half-life from plasma is reported to be about 0.5 to 3 hours. Omeprazole is highly bound (about 95%) to plasma proteins.

INDICATIONS:
It is used in conditions where inhibition of gastric acid secretion may be beneficial including aspiration syndromes, dyspepsia, erosive esophagitis, gastro-

esophageal reflux disease (GERD), benign gastric ulcer, duodenal ulcer, and hypersecretory conditions (e.g. Zollinger-Ellison syndrome).

DOSAGE:
Dyspepsia: Usual dose: 20 mg daily for 2 – 4 weeks.
Gastro-esophageal reflux disease (GERD): Usual dose: 20 mg once daily for 4 weeks. Some patients may require additional 4 weeks of therapy.
Refractory esophagitis: 40 mg daily. Maintenance therapy after healing of esophagitis is 20 mg once daily. In children, doses in the range 0.7 – 1.4 mg per kg body-weight daily, up to a maximum dose of 40 mg, have been given for 4 – 12 weeks.
Peptic ulcer disease: a single dose of 20 mg by mouth, or 40 mg in severe cases. Treatment is continued for 4 weeks for duodenal ulcer and 8 weeks for gastric ulcer. Where appropriate, a dose of 20 mg once daily may be given for maintenance.

NSAID-associated ulceration: 20 mg once daily.
Zollinger-Ellison syndrome: initial recommended dosage is 60 mg once daily. Or as prescribed by the physician.

Prophylaxis of acid aspiration during general anesthesia: 40 mg in the evening before the surgery and 40 mg on the day of surgery, two to six hours before the procedure. Or as prescribed by the physician.

ADVERSE EFFECTS:
Omeprazole is generally well tolerated. Adverse effects are generally mild. The most frequent adverse effects of omeprazole and other proton pump inhibitors are headache, diarrhea and skin rashes. Other adverse effects include pruritus, dizziness, fatigue, constipation, nausea and vomiting, flatulence, abdominal pain, arthralgia and myalgia, urticaria and dry mouth. Isolated cases of photosensitivity, bullous eruptions, erythema multiforme, angioedema, anaphylaxis, increased liver enzymes, hepatitis, jaundice and hepatic encephalopathy have been reported. Occasional insomnia, somnolence, vertigo, reversible confusional states, agitation, depression and hallucinations have occured in severely ill patients.

OVERDOSE AND TREATMENT:
Report on overdosage with omeprazole includes 2 cases. Drowsiness, headache (possibly due to a metabolite), and tachycardia were the major clinical manifestations. Both patients recovered uneventfully without specific treatment.

PRECAUTIONS:
Before giving omeprazole and other proton pump inhibitors, consider the possibility of malignancy in patients with gastric ulcers since these drugs may mask symptoms and delay diagnosis. Omeprazole should be used with caution

in patients with hepatic impairment. Because of their acid - suppressing effects, proton pump inhibitors may increase the risk of gastrointestinal infection.

DRUG INTERACTIONS:
Omeprazole and other proton pump inhibitors are metabolized by the cytochrome P450 system, primarily by isoenzyme CYP2C19, and may alter the metabolism of some other drugs metabolized 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 ketoconazole, and possibly itraconazole, whose absorption is dependent on acid gastric pH.

CONTRAINDICATIONS:
Omeprazole is contraindicated during pregnancy and in patients with history of hypersensitivity to omeprazole.

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

AVAILABILITY:
Strip-foiled capsules 10's x 20 mg (Box of 50's)
Strip-foiled capsules 10's x 40 mg (Box of 50's)

STORE AT TEMPERATURES NOT EXCEEDING 25°C.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph

SVMore

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