GASTRAZOLE ®

Capsules

Omeprazole

Treatment of duodenal and gastric ulcers, reflux oesophagitis and management of Zollinger-Ellison syndrome.

COMPOSITION

Each capsule contains :

5-methoxy-2- (((4-methoxy-3,5-dimethyl-2-pyridinyl) methyl) sulphinyl)-1H- benzimidazole, (omeprazole) ..... 20 mg

PROPERTIES

- GASTRAZOLE (Omeprazole) is the first H^+, K^+-adenosine triphosphatase antagonist available for clinical use.
- GASTRAZOLE inhibits the gastric (H^+, K^+)-ATP ase, a membrane-bound proton pump in the parietal cell, that is the final step in the secretion of gastric acid, in a highly selective and dose-related mechanism of action.
- GASTRAZOLE inhibits basal as well as stimulated gastric secretion irrespective of the stimulus, without any effect on acetylcholine or histamine receptors. Pepsin and intrinsic factor secretion are also unaffected.
- The action of GASTRAZOLE is of rapid onset and persists for 24 to 72 hours.
- Control of gastric acid secretion is achieved with once daily dosing.

INDICATIONS

- **Duodenal or gastric ulcers:**
  - with or without bleeding complications.
  - resistant to conventional therapy (H2- receptor antagonists).
- **Reflux oesophagitis.**
- **Zollinger-Ellison syndrome.**

DOSAGE

Gastric ulcer or reflux oesophagitis :

1-2 capsules (20 - 40 mg) once daily in the morning for 4 - 8 weeks.

Patients who may not have complete healing after four weeks of treatment , may receive an additional four weeks of therapy.

Duodenal ulcer :

1-2 capsules (20 - 40 mg) once daily in the morning for 2 - 4 weeks.

Patients who may not have complete healing after two weeks of treatment, may receive an additional two weeks of therapy.

Zollinger-Ellison syndrome:

The recommended initial dose is 3 capsules (60 mg) daily. Daily doses of 1-6 capsules(20-120 mg) may be given. Doses above 4 capsules (80 mg) daily should be divided into two doses. The dose should be adjusted individually and treatment should be continued as long as clinically indicated.

DRUG-INTERACTIONS

- Since OMEPRAZOLE is metabolised via cytochrome P450 inhibition of hepatic metabolism of certain drugs may be of potential importance.
- Monitoring of patients receiving warfarin is recommended, and a reduction of dose of warfarin may be necessary.
- The clearance of diazepam is reduced by about 50%.
- Omeprazole has only minor effects on the elimination of single oral dose of phenytoin.
- No interaction with propranolol, theophylline or concomitantly administered antacid has been found.

CONTRA-INDICATIONS

Known hypersensitivity to omeprazole.

SIDE-EFFECTS

OMEPRAZOLE is well tolerated. Rarely, transient and mild nausea, headache, diarrhoea, constipation or flatulence may occur.

PRECAUTIONS

- The possibility of malignancy should be excluded.
- As with all new drugs, OMEPRAZOLE should not be given during pregnancy and lactation unless it is considered essential.

DOSAGE-ADJUSTMENT

- Dose adjustment in patients with impaired renal or liver function is not required.
- No dose adjustment is necessary in the elderly.
- There is no experience with OMEPRAZOLE in children.

OVERDOSAGE

- Single oral doses of up to 8 capsules (160 mg) daily have been well tolerated.
- There is no information available on the effect of overdosage in man.

PRESENTATION

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Box containing 14 capsules.

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