OMEPRAZOLE

Gastro - Resistant Omeprazole Capsules BP 40 mg

Composition:
Each hard gelatin capsule contains :
Omeprazole B.P. 40 mg.
(As enteric coated pellets)
Excipients : Q.S.
Approved colour used in capsules shell & pellets.

PHARMACOLOGICAL CLASSIFICATION:
Medicines acting on the gastro-intestinal tract.

PHARMACOLOGICAL ACTION :

Pharmacodynamics
Omeprazole is an inhibitor of the gastric proton pump (H**+,** K+-ATPase). It inhibits both basal and stimulated gastric acid secretion by parietal cells, whether induced by acetylcholine, gastrin or histamine. Omeprazole has no effect on acetylcholine, histamine or gastric receptors.

Pharmacokinetics
Orally administered omeprazole is well absorbed but to a variable extent. Absorption of omeprazole takes place in the small intestine and is usually completed within three to six hours. Bioavailability depends on dose and gastric pH and may reach 70% with repeated administration. Food has no influence on the bioavailability of omeprazole.
Omeprazole is more than 95% bound to plasma proteins Clearance from the circulation is by hepatic metabolism with a plasma half-life of 30 to 90 minutes.
Hepatic metabolism occurs primarily via the cytochrome P450 (CYP) isoform (CYP2C19). The inactive metabolites are excreted mainly in the urine (80%) whilst the remaining 20% are excreted via the faeces. The average half-life of the terminal phase of the plasma concentration-time curve is approximately 40 minutes. There is no change in plasma half- life during treatment. The inhibition of acid secretion is related to the area under the plasma concentration - time curve (AUC) and not to the actual plasma concentration at a given time.

INDICATIONS :

OMEPRAZOLE CAPSULES is indicated in:

Adults : Treatment of duodenal ulcer, including prevention of relapse gastric ulcer and reflux oesophagitis Long-term management of reflux oesophagi tis and Zollinger-Ellison Syndrome_
Symptomatic relief of heartburn in patients with gastro-oesophageal reflux disease (GORD) and the short-term relief of functional dyspepsia.
Helicobacter pylori-positive duodenal ulcers as part of an eradication programme with appropriate antibiotics.
Treatment of non-steroidal anti-inflammatory drugs (NSAID)-associated gastric and/or duodenal ulcer/erosions. Reduction of the risk to develop gastric and/or duodenal ulcer/erosions and reduction of the risk ofrelapse for previously healed gastric and/or duodenal ulcer/erosions in patients on NSAID treatment.

Children : Short-term (up to 3 months) treatment of severe ulcerative reflux oesophagitis resistant to previous medical treatment.

CONTRA- INDICATIONS :
Hypersensitivity to any of the ingredients Safety in pregnancy and lactation has not been established

WARNINGS :
Symptomatic response to OMEPRAZOLE CAPSULES therapy does not preclude the presence of gastric ulcer or malignancy or a malignant disease of the oesophagus.
The administration of OMEPRAZOLE CAPSULES in this situation may delay diagnosis.
Special Precautions. Hepatic impairment may require a reduction in dose.

INTERACTIONS:
OMEPRAZOLE CAPSULES is metabolised via the hepatic P450 cytochrome enzyme system, which may affect the metabolism of other medications metabolised by these enzymes, when given concomitantly. The elimination of diazepam , warfarin and phenytoin may be prolonged when OMEPRAZOLE CAPSULES is given concomitantly.Monitoring of INR and phenytoin serum levels is recommended and dosage reductions may be necessary when OMEPRAZOLE CAPSULES is given concomitantly. There is a possible interaction of OMEPRAZOLE CAPSULES with digoxin and a 10% increase in digoxin bioavailability may be expected.There may be interactions with other medicines, which are also metabolised via the cytochrome P450 enzyme system.

DOSAGE AND DIRECTIONS FOR USE :
OMEPRAZOLE CAPSULES is recommended to be given in the morning and swallowed whole with a half glass of liquid. The capsules should not be chewed or crushed. 20 mg once daily for two to four weeks.
In some duodenal ulcer patients refractory to other treatment regimens, 40 mg once daily may be effective.
There is very limited experience with the use of OMEPRAZOLE CAPSULES in children.
Dose reductions are not necessary in elderly patients.
The long-term safety of OMEPRAZOLE CAPSULES in patients with renal and hepatic impairment has not been established.

SIDE-EFFECTS:
Effects related to acid inhibition:
During long-term treatment gastric glandular cysts have been reported in increased frequency.
These physiological changes result from pronounced inhibition of gastric acid secretion.
Decreased gastric acidity increases gastric counts of bacteria normally present in the gastro-intestinal tract. Treatment with OMEPRAZOLE CAPSULES may lead to an increased risk of gastro-intestinal infections such as Salmonella and Campylobacter. In the presence of symptoms such as significant unintentional weight loss, recurrent vomiting, dysphagia, haematemesis, or melaena, and when gastric ulcer is suspected or present, malignancy should be excluded, as treatment with OMEPRAZOLE CAPSULES may alleviate symptoms and delay diagnosis.

KNOWN SYMPTOMS OF OVER-DOSAGE AND PARTICULARS OF ITS TREATMENT
Blurred vision, confusion, diaphoresis, flushing, headache, malaise, nausea and tachycardia have been reported from over-dosage with omeprazole. There is no specific antidote for overdose with omeprazole.

TREATMENT IS SYMPTOMATIC AND SUPPORTIVE
Due to extensive protein binding omeprazole is not readily dialysable_ Patients in whom overdose is confinned or suspected should be referred for medical practitioner/ doctor consultation.

PRESENTATION :
OMEPRAZOLE CAPSULES: 2x7 capsules

STORAGE:
Store at a temperature below 30°C.

Protect from light.

Keep all medicines out of reach of children.