Omel

Omeprazole

COMPOSITION:

Omel 20 Capsule: Each delayed release capsule contains Omeprazole BP 20 mg as enteric pellets.

Omel 40 Capsule: Each delayed release capsule contains Omeprazole BP 40 mg as enteric pellets.

PHARMACOLOGY:

Omeprazole is a substituted benzimidazole that suppresses gastric acid secretion by specific inhibition of the gastric acid proton pump (H^+/K^+-ATPase enzyme system) at the secretory surface of the gastric parietal cell. It blocks the final step of acid production. After oral administration, the onset of the antisecretory effect of Omeprazole occurs within one hour, with the maximum effect occurring within two hours and the duration of inhibition lasts up to 72 hours. The antisecretory effect lasts far longer than would be expected from the very short (less than one hour) plasma half-life, apparently due to prolonged binding to the parietal H^+/K^+-ATPase enzyme. Following absorption, Omeprazole is almost completely metabolized and rapidly eliminated mostly through urine.

INDICATION:

Omel is indicated in the treatment of-

Heartburn, Any symptoms of GERD, Erosive esophagitis (both curative and maintenance therapy), Duodenal ulcer, Gastric ulcers, Reduction of risk of upper GI bleeding in critically ill patients.

DOSAGE AND ADMINISTRATION:

Duodenal ulcer: 20 mg once daily for 4 weeks. In severe cases, 40 mg once daily for 4 weeks. ***Gastric ulcer:*** 20 mg once daily for 8 weeks. In severe cases, 40 mg once daily for 8 weeks. ***Erosive Reflux Esophagitis:*** 20 mg once daily for 4 weeks. For those not fully healed, to be continued for 4 more weeks. ***Refractory Reflux Esophagitis:*** 40 mg once daily for 8 weeks. ***Gastro-esophageal reflux disease:*** 20 mg once daily for 4 weeks, continued for further 4-8 weeks if not fully healed; 40 mg once daily has been given for 8 weeks in gastro-oesophageal reflux disease refractory to other treatment; maintenance 20 mg once daily. ***Acid reflux disease*** (long-term management), 10 mg daily increasing to 20 mg once daily if symptoms return. ***Acid-related dyspepsia:*** 10-20 mg once daily for 2-4 weeks according to response. ***Zollinger-Ellison Syndrome:*** 60 mg once daily, adjusted individually and continued as long as necessary. Most patients will be effectively controlled with 20-120 mg daily. Dosage above 80 mg should be divided and given twice daily.

CONTRAINDICATION:

Omeprazole is contraindicated in patients with known hypersensitivity to any components of the formulation.

SIDE EFFECTS:

Omeprazole is well tolerated and adverse reactions have generally been mild and reversible. Side-effects may include headache, diarrhoea, constipation, abdominal pain, nausea/vomiting and flatulence, dizziness, paraesthesia, somnolence, insomnia and vertigo, increased liver enzymes, rash, dermatitis and/or pruritis, urticaria, malaise.

Others include hypersensitivity reactions e.g. angioedema, fever, bronchospasm, interstitial nephritis and anaphylactic shock.

PRECAUTIONS:

Symptomatic response to therapy with Omeprazole does not preclude the presence of gastric malignancy. Immediate Release Omeprazole formulations contain sodium bicarbonate which should be taken into consideration for patients on a Sodium-restricted diet.

USE IN PREGNANCY AND LACTATION:

Pregnancy: There are no adequate and well-controlled studies on the use of Omeprazole in pregnant women. Therapeutic doses during pregnancy are unlikely to pose a substantial teratogenic risk. Omeprazole should be used during pregnancy only if the potential benefit to pregnant women justifies the potential risk to the fetus.

Lactation: Omeprazole is excreted in human milk. Thus, a decision should be taken to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

DRUG INTERACTION:

Omeprazole can prolong the elimination of drugs that are metabolized by oxidation in the liver such as Diazepam, Warfarin and Phenytoin. Drugs that are metabolized by the cytochrome P-450 system such as cyclosporin, disulfiram, and benzodiazepines have been reported to show interactions with Omeprazole. Normal subjects did not show any interaction with theophylline and propranolol.

OVERDOSAGE:

Symptoms were transient, and no serious clinical outcome has been reported with Omeprazole overdose. No specific antidote for Omeprazole overdose is known. Omeprazole is extensively bound with protein and is, therefore, not readily dialyzable. In the event of overdose, treatment should be symptomatic and supportive.

PHARMACEUTICAL PRECAUTION:

It should be stored in a cool and dry place, protected from light and moisture.

HOW SUPPLIED:

Omel 20 Capsule: Each box contains 10 x10 capsules in Alu-Alu blister pack.

Omel 40 Capsule: Each box contains 3 x10 capsules in Alu-Alu blister pack.

Manufactured by:

MEDICON Pharmaceuticals Ltd
Mirpur, Dhaka, Bangladesh