

Onelock

Omeprazole BP

Composition

Onelock 20 capsule : Each capsule contains Omeprazole BP 20 mg as enteric coated 8.5% pellets.
Onelock 40 capsule : Each capsule contains Omeprazole BP 40 mg as enteric coated 8.5% 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) at the secretory surface of the gastric parietal cell. It blocks the final step of acid secretion. 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

Onelock (Omeprazole) is indicated for the treatment of-
Heartburn, Any symptoms of GERD, Erosive esophagitis (both curative and maintenance therapy), Duodenal ulcer, Gastric ulcer, Reduction of risk of upper GI bleeding in critically ill patients.

Dose and Administration

Route of administration: Oral

Onelock (Omeprazole) should be taken before meal. No dosage adjustment is necessary for patients with renal impairment, hepatic dysfunction or for the elderly.

Duodenal Ulcer: The recommended adult oral dose is 20 mg once daily. Most patients heal within four weeks. Some patients may require an additional four weeks of therapy.

Gastric Ulcer: The recommended adult oral dose is 40 mg once a day for 4-8 weeks.

Gastroesophageal Reflux Disease (GERD): The recommended adult oral dose is 20 mg daily for up to 4 weeks.

Erosive esophagitis: The recommended adult oral dose is 20 mg daily for 4 to 8 weeks.

Zollinger-Ellison syndrome: The recommended adult oral starting dose is 60 mg once a day. Dosage should be adjusted to individual patient needs and should continue for as long as clinically indicated. Doses up to 120 mg t.i.d. have been administered. Daily dosages of greater than 80 mg should be administered in divided doses.

Contraindication

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

Warning & Precaution

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.

Side Effects

Common: 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.

Rare: Hypersensitivity reactions e.g. angioedema, fever, bronchospasm, interstitial nephritis and anaphylactic shock.

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.

Use in Children & Adolescents

Not recommended for children below 12 years of age.

Drug interactions

With Medicine: Omeprazole can prolong the elimination of Diazepam, Warfarin, Phenytoin and other vitamin K antagonists. No interaction with Theophylline or Propranolol was found. There have been clinical reports of interaction with other drugs metabolized via the cytochrome P-450 system e.g. Cyclosporine, Disulfiram, Benzodiazepines. Patients should be monitored to determine if it is necessary to adjust the dosage of these drugs when taken concomitantly with Omeprazole.

With food & others: May reduced absorption due to presence of food.

Overdose

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.

Storage

Store below 30° C temperature. Keep in dry place, away from light. Keep out of reach of children.

Packing

Onelock 20 capsule : Each box contains 6 alu-alu blister of 10 capsules.

Onelock 40 capsule : Each box contains 3 alu-alu blister of 10 capsules.