Omesil®

Omeprazole

Presentation
Omesil® 20 capsule : Each capsule contains Omeprazole BP 20 mg as enteric coated pellets.
Omesil® 40 capsule : Each capsule contains Omeprazole BP 40 mg as enteric coated pellets.

Description
Omesil® (Omeprazole) is a specific inhibitor of the gastric proton pump (H^+/K^+ ATPase) in the parietal cell. There it produces dose dependent inhibition of acid secretion by binding to the enzyme and effectively reduces gastric acid secretion. This effect leads to inhibition of both basal and stimulated acid secretion irrespective of the stimulus. After oral administration, the onset of the antisecretory effect of Omeprazole occurs within one hour, with the maximum effect occurring within two hours and inhibition of secretion lasts up to 72 hours. When the drug is discontinued, secretory activity returns gradually over 2 to 5 days.

Indications
Omesil® (Omeprazole) is indicated in the treatment of -
* Heartburn
* Duodenal ulcer
* Any symptoms of GERD
* Gastric ulcers
* Erosive esophagitis (both curative and maintenance therapy)
* Reduction of risk of upper GI bleeding in critically ill patients

Dosage & administration
Omesil® (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. ***Gastroesophageal Reflux Disease (GERD):*** The recommended adult oral dose is 20 mg daily for up to 4 weeks. ***Gastric Ulcer:*** The recommended adult oral dose is 40 mg once a day for 4-8 weeks. ***Erosive esophagitis:*** The recommended adult oral dose is 20 mg daily for 4-8 weeks. ***Reduction of risk of upper gastrointestinal bleeding in critically ill patients:*** The recommended adult oral dose of Omeprazole powder for suspension is 40 mg initially, followed by 40 mg after 6-8 hours as a loading dose on the first day, then 40 mg once daily for up to 14 days. The use of Omeprazole powder for suspension in critically ill patients beyond 14 days has not been evaluated. ***Zollinger-Ellison syndrome:*** The recommended adult oral starting dose is 60 mg once a day. Doses should be adjusted to individual patients 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.

Side effects
Omeprazole is generally well tolerated. Mild to transient nausea, vomiting, dizziness, abdominal pain, diarrhoea, headache etc. have been reported and not requiring a reduction in dosage.

Precautions
Symptomatic response to therapy with Omeprazole does not preclude the presence of gastric malignancy. Omeprazole powder for suspension contains sodium bicarbonate, which should be taken into consideration for patients on a sodium-restricted diet.

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

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 interactions
Omeprazole can prolong the elimination of diazepam, warfarin and phenytoin. 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.

Directions for use of powder for suspension
Whole contents of the sachet should be taken into a small glass containing 2-3 teaspoonful of water. Other liquids or foods should not be used. The mixer should be stirred well and drink immediately. The glass should be refilled with water and drink. If the suspension is to be administered through a nasogastric or orogastric tube, the suspension should be constituted with approximately 20 ml of water. Other liquids or foods should not be used. The mixer should be stirred well and administered immediately. An appropriately sized syringe should be used to instill the suspension in the tube. The suspension should be washed through the tube with 20 ml of water.

Pharmaceutical precaution
Patients should be cautioned that the **Omesil®** formulations should not be chewed or crushed, and should be swallowed whole. **Omesil®** should be stored in a cool and dry place, away from light. Keep out of the reach of children.

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 protein bound and is therefore, not readily dialyzable. In the event of overdose, treatment should be symptomatic and supportive.

Commercial pack
Omesil® 20 capsule: Each box contains 10 alu-alu blister strips of 10 capsules.
Omesil® 40 capsule: Each box contains 5 alu-alu blister strips of 4 capsules

Manufactured by :
Silva
Pharmaceuticals Limited
Maijdee, Noakhali, Bangladesh