

Ometem[®]

Omeprazole

COMPOSITION:

Ometem[®] 20 Capsule: Each capsule contains Omeprazole enteric coated pellets equivalent to Omeprazole BP 20 mg.

Ometem[®] 40 Capsule: Each capsule contains Omeprazole enteric coated pellets equivalent to Omeprazole BP 40 mg.

PHARMACOLOGY:

Omeprazole is an inhibitor of gastric acid secretion. It inhibits gastric acid secretion by blocking Hydrogen-Potassium-Adenosine triphosphatase (proton pump) enzyme system in the gastric parietal cell. After oral administration, the onset of the anti-secretory effect occurs within one hour, with the maximum effect occurring within two hours and inhibition of secretion lasts up to 72 hours. Omeprazole is almost completely metabolized and rapidly eliminated mostly in the urine. Although the elimination half-life from plasma is short, being reported to be 0.5 to 1.5 hours. Omeprazole is highly bound (about 95%) to plasma proteins.

INDICATION:

Ometem[®] Capsule is indicated for the treatment of gastroesophageal reflux disease including reflux esophagitis, acid reflux disease, duodenum gastric ulcers, *Helicobacter pylori* eradication in peptic ulcer disease, prophylaxis of acid aspiration, Zollinger-Ellison syndrome and for the treatment of NSAID-associated gastric ulcers, duodenal ulcers or gastroduodenal erosions.

DOSE & ADMINISTRATION:

Ometem[®] Capsule should be taken before meal.

Benign gastric and duodenal ulcers including those complication in NSAIDs therapy: 20 mg daily for 4 weeks in duodenal ulceration or 8 weeks in gastric ulceration, in severe cases the dose may be increased to 40 mg daily; long-term use is not recommended.

Healing of reflux esophagitis: 20 mg daily for 4 weeks, followed by a further 4-8 weeks if not fully healed; 40 mg daily has been given for 8 weeks in reflux esophagitis, refractory to other treatment; may be continued at 20 mg daily.

Helicobacter pylori eradication regimen in peptic ulcer disease: Ometem[®] Capsule is recommended at a dose of 20 mg twice daily in association with antimicrobial agents.

Zollinger-Ellison syndrome: Initially 60 mg once daily; usual range 20-120 mg daily (above 80 mg in 2 divided doses). Larger doses of upto 180 mg daily in divided doses may be used or as prescribed by the physicians.

Paediatric use in severe ulcerating reflux esophagitis (Child > 1 year): If body-weight 10-20 kg, 10-20 mg once daily for 4-12 weeks; if body-weight over 20 kg, 20-40 mg once daily for 4-12 weeks.

CONTRA-INDICATION:

Ometem[®] Capsule is contraindicated in patients with known hypersensitivity to any component of the formulation.

WARNING AND PRECAUTION:

Symptoms response to therapy with Ometem[®] Capsule does not preclude the presence of gastric malignancy.

SIDE EFFECTS:

Ometem[®] Capsule is well tolerated; nausea, vomiting, diarrhea, abdominal pain, paresthesia, dizziness and headache have been stated. These events are mild and transient and not required a reduction of dosage.

USE IN PREGNANCY & LACTATION:

Pregnancy: There are no adequate and well controlled studies on the use of Omeprazole in pregnant women. 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:

Omeprazole is FDA-approved for use in pediatric patients as young as 1 month of age.

DRUG INTERACTION:

Omeprazole can prolong the elimination of diazepam, warfarin and phenytoin. So, reduction of warfarin or phenytoin dose may be necessary when Omeprazole is added to the treatment. There is no evidence of an interaction of Omeprazole with theophylline, propranolol or antacids.

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 in a dry and cool place below 30° C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:

Ometem[®] 20 Capsule: Each box contains 10x10's capsules in Alu-Alu blister pack.

Ometem[®] 40 Capsule: Each box contains 5x4's capsules in Alu-Alu blister pack.



Manufactured by

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