



Omeprazole Capsule



Each Hard Gelatin Capsules contains
Omeprazole BP.....20 mg
(as enteric coated granules)
Excipients QS

Composition :

Omeprazole -10 Capsules

Each capsule contains Omeprazole 10 mg (enteric coated granules)

Omeprazole -20 Capsules

Each capsule contains Omeprazole 20 mg (enteric coated granules)

Description :

Omeprazole is a substituted benzimidazole that suppresses gastric acid secretion by specific inhibition of the H⁺ /K⁺ -ATPase enzyme system (proton pump) at the secretory surface of the gastric parietal cell thus blocking the final step of acid production.

Indications :

Omeprazole is indicated for short-term treatment of active duodenal ulcer, short-term treatment (4-8 weeks) of active benign gastric ulcer, treatment of heartburn and other symptoms associated with GERD, short-term treatment (4-8 weeks) of erosive esophagitis, Maintenance of Healing of Erosive Esophagitis and for the long-term treatment of pathological hypersecretory conditions (eg, Zollinger-Ellison syndrome).

Dosage and Administration :

Omeprazole capsules should not be opened, chewed or crushed and should be swallowed whole. The capsule should be taken before meals.

Duodenal ulcers

20 mg once daily for four weeks.

Gastric ulcers

20 mg once daily for eight weeks. In severe cases it can be increased to 40 mg once daily.

Gastroesophageal reflux disease

20 mg-40 mg daily for 4-8 weeks.

GERD, long-term management

10 mg once daily, dose may be increased to 20 mg once daily if symptoms return.

Zollinger Ellison syndrome

Initial dose is 60 mg daily. It is to be adjusted as per the individual requirement and continued till clinically indicated. The patients are usually effectively controlled on doses of 20 mg–120 mg daily. With doses above 80 mg the dose should be divided and given twice daily.

Contraindications :

Hypersensitivity to the components of the formulation.

Warnings and Precautions :

Drug Interactions

Drugs metabolised in the liver :

Omeprazole can prolong the elimination of diazepam, warfarin and phenytoin which are metabolised by oxidation in the liver. Hence, at the time of concomitant administration, dosage adjustment should be done after careful monitoring of the patient.

Ketoconazole, ampicillin esters and iron salts: Because of its profound and long lasting inhibition of gastric acid secretion, omeprazole may interfere with the absorption of these drugs as gastric pH is an important determinant of their bioavailability.



**Pregnancy :**

There are no adequate or well-controlled studies of omeprazole in pregnancy. Omeprazole should be used during pregnancy only if potential benefits outweigh potential risks.

Lactation :

It is not known whether omeprazole is secreted in breast milk. But, because of the potential for adverse effects, a decision should be made whether to discontinue nursing or to discontinue the drug.

Paediatric Use :

Safety and effectiveness of omeprazole in children has not been established.

Side Effects :

Nausea, headache, diarrhoea, constipation and flatulence are reported rarely with administration of omeprazole. These events are mild and transient and there has been no consistent relationship with the treatment.

Overdosage :

Reports have been received of overdosage with omeprazole in humans. Doses ranged up to 2400 mg (120 times the usual recommended clinical dose). Manifestations were variable, but included confusion, drowsiness, blurred vision, tachycardia, nausea, vomiting, diaphoresis, flushing, headache, dry mouth, and other adverse reactions similar to those seen in normal clinical experience. Symptoms were transient, and no serious clinical outcome has been reported when omeprazole was taken alone. No specific antidote for omeprazole overdosage is known. Omeprazole is extensively protein bound and is, therefore, not readily dialyzable. In the event of overdosage, treatment should be symptomatic and supportive.

Presentation :

Omeprazole - 10 Blister pack of 10 capsules

Omeprazole - 20 Blister pack of 10 capsules

For Information about Generic Medicines : genericmedicines@tajpharma.com

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According to the Indian Trade Mark the company owns about 450 brands and 4600 generic manufacturing permissions in India. According to the export data analysis the company was the largest exporter of generic medicines to the Europe and Middle East countries.

www.tajpharma.com

The company medicines are present in France, Georgia, Egypt and CIF countries.



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