

Omiz®

Omeprazole Capsules

Composition:

Omiz 10: Each capsule contains Omeprazole enteric coated pellets equivalent to Omeprazole 10 mg.

Omiz 20: Each capsule contains Omeprazole enteric coated pellets equivalent to Omeprazole 20 mg.

Excipients: Mannitol, lactose, sucrose, hydroxypropyl methylcellulose, hydroxypropyl methylcellulose phthalate, sodium lauryl sulfate, disodium hydrogen phosphate, cetyl alcohol and titanium dioxide.

Properties:

Omiz (Omeprazole) belongs to a class of anti-secretory compounds called benzimidazoles. Its mechanism of action includes the suppression of gastric acid secretion by specific inhibition of the H⁺/K⁺ ATPase enzyme system at the secretory surface of the gastric parietal cell. That is why it has been characterized as a gastric acid-pump inhibitor.

Absorption of Omeprazole is rapid, with peak plasma levels occurring within 0.5 to 3.5 hours, proportional to doses up to 40mg. Plasma half-life is 0.5 to 1 hour, and the total body clearance is 500 to 600 ml/min. Protein binding is approximately 95%.

The majority of the administered dose is eliminated in urine, the remainder of the dose was recoverable in feces, this implies a significant biliary excretion of the metabolites of Omeprazole.

Indications:

Omiz (Omeprazole) is indicated for the treatment of various stomach or esophagus problems related to excess stomach acids e.g. Gastroesophageal Reflux Disease (GERD), certain types of ulcers e.g. Active Duodenal ulcer and Benign Gastric ulcer, Zollinger-Ellison Syndrome, Erosive esophagitis and Helicobacter Pylori infection together with other medications.

Contraindications:

Omiz (Omeprazole) is contraindicated for patients with known hypersensitivity to any of its components.

Precautions:

Omeprazole should be used only when clearly needed during pregnancy.

Breast-feeding is not recommended while taking this drug.

Any medical history of liver or kidney disease should be reported to the doctor before using this medication.

Omeprazole capsules should be taken before eating. Swallowed as a whole, not opened, chewed or crushed.

Interactions with other drugs:

Omeprazole can prolong the elimination of Diazepam, Warfarin and Phenytoin. Patients taking Omeprazole should be monitored to adjust the dosage of these medications when taken concurrently.

Omeprazole may interfere with absorption of drugs where gastric pH is an important determinant to their bioavailability (e.g. ketoconazole, itraconazole, ampicillin esters, and iron salts).

The co-administration of Omeprazole with Clarithromycin or Digoxin have resulted in increase in plasma levels of Clarithromycin and Digoxin.

Warnings:

Symptomatic response to therapy with Omeprazole does not preclude the presence of gastric malignancy. Atrophic gastritis has been noted occasionally in gastric biopsies from patients treated long-term with Omeprazole.

Dosage and Administration:

Omiz (Omeprazole) is administered according to the condition: Gastroesophageal Reflux Disease:

The recommended oral dose is 20mg daily for up to four weeks.

Short-term treatment of active Duodenal Ulcer:

The recommended adult oral dose is 20mg once daily, some patients may heal within four weeks, others may require additional four weeks of therapy.

Gastric Ulcer:

The recommended adult oral dose is 40mg once daily for 4-8 weeks.

Healing of Erosive Esophagitis:

The recommended adult oral dose is 20mg daily

Overdosage:

Rare reports have been received of over-dosage with Omeprazole. However, manifestations include confusion, drowsiness, blurred vision, tachycardia, nausea, diaphoresis, flushing, headache and dry mouth.

In events of overdosage treatment should be symptomatic and supportive.

Side Effects:

Omiz (Omeprazole) is generally well tolerated. The following adverse effects were reported: Allergic reactions including: fever, pain, Rash, Itching, Fatigue, and Abdominal Swelling. Chest Pain, Tachycardia, Palpitations, Anorexia, flatulence, Diarrhea, Constipation, Dry mouth, Unusual thirst, Back or Joint Pain, Nervousness, Confusion, Sleep disturbances, Ringing in the ears, Urinary Tract Infection, Changes in amount of urine, and Taste prevention.

Consult your Pharmacist or Physician if any side effect is observed.

Pharmaceutical Precautions:

Keep at room temperature (15 - 30 °C).

Do not use beyond the expiry date or if the product shows any sign of deterioration.

Presentations:

Omiz 10: Pack of 14 capsules.

Omiz 20: Pack of 14 capsules.

Hospital packs are available.

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THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Strictly follow the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists.



Manufactured by:

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