

OMELOR

20mg, 40mg
Capsule / Sachets

(O M E P R A Z O L E)

اومی لور ۲۰ ملی گرام کپسول
(اومی پرازول) ۴۰ ملی گرام کپسول / ساشے

DESCRIPTION:

Omelor (Omeprazole) is a medication used in the treatment of gastroesophageal reflux disease (GERD), peptic ulcer disease, and Zollinger-Ellison syndrome. It is also used to prevent upper gastrointestinal bleeding. Omeprazole is a proton-pump inhibitor (PPI) and its effectiveness is similar to other PPI. The empirical formula of Omeprazole is $C_{17}H_{19}N_3O_3S$ and its M.W is 345.4g/mol
Structure:

COMPOSITION:

Omelor 20 capsule:

Each capsule contains:

Enteric coated pellets of Omeprazole Eq to Omeprazole USP...20mg

Omelor 40 mg capsule:

Each capsule contains:

Enteric coated pellets of Omeprazole Eq to Omeprazole USP...40mg

Each Sachets contains:

Omeprazole.....40mg

Sodium Bicarbonate.....1680mg

CLINICAL PHARMACOLOGY:

Pharmacokinetics:

Absorption: Absorption of Omeprazole occurs rapidly; with peak plasma concentrations of Omeprazole achieved within 0.5-3.5 hours Absolute bio-availability (compared with intravenous administration) is approximately 30-40% at doses of 20-40mg, largely due to pre-systemic metabolism

Distribution: Approximately 0.3L/kg, corresponding to the volume of extracellular water.

Elimination: Renal 72 to 80%.

Fecal, 18 to 20%. In dialysis not readily dialyzable, because of extensive protein binding.

MECHANISM OF ACTION:

Omeprazole is a benzimidazole with selective and irreversible proton pump inhibition activity. Omeprazole forms a stable disulfide bond with the sulfhydryl group of the hydrogen-potassium ($H^+ - K^+$)ATPase found on the secretory surface of parietal cells, thereby inhibiting the final transport of hydrogen ions (via exchange with potassium ions) into the gastric lumen and suppressing gastric acid secretion. This agent exhibits no anticholinergic activities and does not antagonize histamine H2 receptors.

INDICATION AND USAGE:

- Duodenal Ulcer (adults)
- Gastric Ulcer (adults)
- Treatment of Gastroesophageal Reflux Disease (GERD) (adults and pediatric patients)
- Maintenance of Healing of Erosive Esophagitis (adults and pediatric patients)
- Pathological Hypersecretory Conditions (adults)
- Reflux esophagitis
- Zollinger-Ellison syndrome
- Peptic Ulcers Associated with Non-steroidal Anti-Inflammatory Drugs (NSAIDs)

DOSE AND ADMINISTRATION:

Short-Term Treatment of Active Duodenal Ulcer is 20mg once daily. Most patients heal within four weeks.

Gastric Ulcer the recommended adult oral dose is 40mg once daily for 4-8 weeks.

Gastroesophageal Reflux Disease (GERD)

The recommended adult oral dose for the treatment of patients with symptomatic GERD and no esophageal lesions is 20mg daily for up to 4 weeks.

Maintenance of healing of Erosive Esophagitis

The recommended adult oral dose is 20mg daily.

Pathological Hypersecretory Conditions

The recommended adult oral starting dose is 60mg one daily. Doses should be adjusted to individual patient needs and should continue for as long as clinically indicated.

CONTRAINDICATIONS:

Omelor Capsules are contraindicated in patients with known hypersensitivity to substituted benzimidazoles or to any component of the formulation. Hypersensitivity reactions may include anaphylaxis, anaphylactic shock, angioedema, bronchospasm, interstitial nephritis and urticaria.

WARNINGS AND PRECAUTIONS:

Concomitant Gastric Malignancy

Symptomatic response to therapy with **Omelor** does not preclude the presence of gastric malignancy.

Atrophic Gastritis

Atrophic gastritis has been noted occasionally in gastric corpus biopsies from patients treated long-term with **Omelor**.

DRUG INTERACTIONS:

Interference with Anti-retroviral Therapy

Concomitant use of Atazanavir and nelfinavir with proton pump inhibitors is not recommended.

Drugs for which pH can affect bio-availability

Because of its profound and long lasting inhibition of gastric acid secretion, it is theoretically possible that omeprazole may interfere with absorption of drugs where gastric pH is an important determinant of their bio-availability effects on Hepatic Metabolism/Cytochrome P-450 Pathways **Omelor** can prolong the elimination of diazepam, warfarin and phenytoin, drugs that are metabolized by oxidation in the liver.

Tacrolimus

Concomitant administration of omeprazole and tacrolimus may increase the serum levels of tacrolimus

POSSIBLE SIDE EFFECTS:

Adverse effects occurring in at least 1% of people include:

- Central nervous system: headache (7%), dizziness (2%)
- Respiratory: upper respiratory tract infection (2%), cough (1%)
- Gastrointestinal: abdominal pain (5%), diarrhea (4%), nausea (4%), vomiting (3%), flatulence (3%), acid regurgitation (2%), constipation (2%)
- Neuromuscular and skeletal: back pain (1%), weakness (1%)
- Dermatologic: rash (2%)

Other concerns related to adverse effects are:

- Recurrence of Clostridium difficile associated diarrhea
- Osteoporosis-related fractures
- Hypomagnesemia

STORAGE & INSTRUCTIONS:

Keep out of the reach of children & store below 30° C.

Protect from sunlight & moisture.

Improper storage may deteriorate the medicine.

Do not use this medicine after the expiry date which is stated on the blister.

PRESENTATION:

Omelor 20mg, 40mg capsule are available in blister pack of 14's.

Omelor Sachets in a pack of 14's.

Manufactured by :



PHARMA LORD | 12km, Lahore
(PVT.) LIMITED | Road, Layyah.
Pakistan
www.pharma-lord.com

اومی لور ۲۰ ملی گرام کپسول
(اومی پرازول) ۴۰ ملی گرام کپسول، ساشے
خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایت: بچوں کی پہنچ سے دور رکھیں۔
دوا کو دھوپ، گرمی اور نمی سے محفوظ رکھیں۔ ڈگری سینٹی گریڈ
سے کم درجہ حرارت پر رکھیں۔