

Brand: Gerzole 40

Generic Name: Omeprazole

Dosage Form: Oral Capsule

Strength of Gerzole 40: Omeprazole 40 mg

Omeprazole in Gerzole 40 is a proton pump inhibitor (PPI) used primarily to treat conditions like gastroesophageal reflux disease (GERD), peptic ulcers, gastritis, and *Helicobacter pylori* infections. It works by reducing the production of stomach acid, which can help alleviate symptoms and promote healing of the gastrointestinal tract.

Mechanism of Action (MOA) of Omeprazole: Gerzole 40

1. Inhibition of the Proton Pump (H⁺/K⁺ ATPase):

- Omeprazole acts by irreversibly inhibiting the proton pump, which is the H⁺/K⁺ ATPase enzyme located on the parietal cells of the stomach lining.
- The proton pump is responsible for the final step in the secretion of hydrochloric acid (HCl) into the stomach. This pump exchanges potassium ions (K⁺) from the inside of the parietal cell with hydrogen ions (H⁺) from the cytoplasm into the stomach lumen, thus contributing to acid production.
- By inhibiting this enzyme, omeprazole reduces the secretion of gastric acid into the stomach. This leads to a significant decrease in gastric acidity, which can help relieve symptoms of acid reflux, promote ulcer healing, and prevent further irritation of the gastrointestinal lining.

2. Irreversible Inhibition:

- Omeprazole undergoes activation in the acidic environment of the stomach to form its active sulfonamide derivative, which binds to the proton pump and irreversibly inactivates it.
- Once the proton pump is inhibited, it cannot secrete acid, and the acid production process is stopped. This effect is long-lasting, as the proton pump must be synthesized anew to restore acid secretion, which typically takes 24-48 hours.

3. Reduction in Gastric Acid Secretion:

- Omeprazole lowers gastric acid secretion, leading to a higher pH in the stomach, which can help:
 - Heal peptic ulcers by reducing the irritation caused by acid.
 - Relieve symptoms of GERD, such as heartburn, by reducing acid reflux into the oesophagus.

- Prevent damage to the oesophagus in conditions like erosive esophagitis.
- Aid in *H. pylori* eradication when used in combination with antibiotics, as a less acidic environment enhances the effectiveness of antibiotics against the bacteria.

4. Pharmacokinetics:

- Omeprazole is absorbed in the small intestine and then metabolized in the liver via the CYP2C19 and CYP3A4 enzymes.
- It is usually taken before meals because food can delay its absorption, and it works most effectively when taken on an empty stomach.

Summary of MOA: Gerzole 40

- Omeprazole inhibits the H⁺/K⁺ ATPase enzyme (proton pump) on the parietal cells of the stomach, leading to a decrease in gastric acid secretion.
- The irreversible inhibition of the proton pump significantly reduces stomach acidity and helps treat conditions related to acid overproduction, such as GERD, peptic ulcers, and gastritis.

1. Indications and Usage: Gerzole 40

Omeprazole is a proton pump inhibitor (PPI) used in the treatment of the following conditions:

- **Gastroesophageal Reflux Disease (GERD):**
 - Treatment of erosive esophagitis due to GERD.
 - Maintenance of healing of erosive esophagitis.
 - Symptomatic treatment of GERD (heartburn).
- **Peptic Ulcer Disease:**
 - Healing of duodenal and gastric ulcers.
 - Maintenance of healed ulcers.
- **Helicobacter pylori Eradication:**
 - Used in combination with antibiotics (e.g., amoxicillin and clarithromycin) for the eradication of *H. pylori* in patients with peptic ulcers.
- **Zollinger-Ellison Syndrome:**
 - Treatment of conditions associated with hypersecretion of gastric acid.
- **NSAID-Induced Ulcers:**
 - Prevention of gastric ulcers in patients requiring NSAID therapy.

2. Dosage and Administration: Gerzole 40

Adults:

- **Gastroesophageal Reflux Disease (GERD):**
 - **Erosive Esophagitis:** 20 mg to 40 mg once daily for 4-8 weeks.
 - **Maintenance Therapy for GERD:** 20 mg once daily.
 - **Symptomatic GERD:** 20 mg once daily for 4 weeks.
- **Duodenal Ulcer:** 20 mg once daily for 4 weeks.
- **Gastric Ulcer:** 40 mg once daily for 4-8 weeks.
- **Helicobacter pylori Eradication (in combination with antibiotics):** 20 mg once daily with appropriate antibiotics for 7-14 days.
- **Zollinger-Ellison Syndrome:** Initial dose of 60 mg once daily; adjust according to clinical response. Doses may be increased up to 120 mg per day, divided into two doses.
- **NSAID-Induced Ulcers (Prevention):** 20 mg once daily.

Pediatric Use:

- **Children (1 year and older):**
 - **GERD:** 5 mg to 20 mg once daily depending on weight and age.
 - **Peptic Ulcer Disease (H. pylori eradication):** Omeprazole should be used in combination with other antibiotics as part of the therapy.

Elderly:

- **No specific dosage adjustment is required. However, elderly patients may be at increased risk of certain side effects such as bone fractures, kidney disease, and hypomagnesemia.**

3. Contraindications:

- **Hypersensitivity:** Omeprazole is contraindicated in patients with known hypersensitivity to omeprazole or any component of the formulation.
- **Concomitant use with clopidogrel:** Omeprazole should generally not be used together with clopidogrel due to the potential reduced effectiveness of clopidogrel.

4. Warnings and Precautions:

- **Gastrointestinal Effects:**
 - **Clostridium difficile-Associated Diarrhea (CDAD):** Use with caution in patients at risk for CDAD.

- **Bone Fractures:** Long-term use of PPIs may increase the risk of bone fractures, especially in elderly patients or those with risk factors for osteoporosis.
- **Hypomagnesemia:** Long-term therapy (greater than 1 year) can lead to low magnesium levels, which may cause serious complications like arrhythmias, seizures, or muscle spasms.
- **Vitamin B12 Deficiency:** Prolonged use of omeprazole may lead to vitamin B12 deficiency.
- **Kidney Concerns:**
 - **Acute Interstitial Nephritis:** Omeprazole can cause acute interstitial nephritis (kidney inflammation). Discontinue if kidney problems arise.
- **Hypersensitivity Reactions:**
 - **Serious allergic reactions, including anaphylaxis and angioedema, have been reported.**
- **Systemic Lupus Erythematosus (SLE):**
 - **In rare cases, omeprazole may exacerbate symptoms of lupus or cause drug-induced lupus erythematosus.**

5. Drug Interactions:

- **Clopidogrel:** Omeprazole may reduce the effectiveness of clopidogrel, a blood-thinning drug, increasing the risk of clot formation. Avoid co-administration if possible.
- **Warfarin:** Omeprazole may interact with warfarin and affect the INR (International Normalized Ratio), requiring more frequent monitoring.
- **Methotrexate:** Omeprazole may increase methotrexate concentrations in the blood, particularly in high-dose regimens.
- **Other Medications:**
 - **Diazepam, phenytoin:** Omeprazole may increase plasma concentrations of these drugs, requiring monitoring for toxicity.
 - **Cyclosporine:** The absorption of cyclosporine may be altered when used with omeprazole, necessitating dose adjustments.

6. Adverse Reactions:

- **Common:**
 - **Headache**
 - **Diarrhea**
 - **Nausea**

- Vomiting
- Abdominal pain
- Flatulence
- **Serious:**
 - Hypomagnesemia: Serious complications such as seizures, arrhythmias, and muscle spasms.
 - Clostridium difficile-associated diarrhea
 - Acute interstitial nephritis (kidney inflammation)
 - Bone fractures
 - Severe allergic reactions (e.g., anaphylaxis, angioedema)

7. Use in Specific Populations:

- **Pregnancy:**
 - **Category C (Risk cannot be ruled out).** Omeprazole should only be used during pregnancy if the potential benefit justifies the potential risk to the fetus.
- **Lactation:**
 - Omeprazole is excreted in breast milk. Use with caution while breastfeeding and consult a healthcare provider before starting treatment.
- **Pediatric Use:**
 - For children 1 year of age or older, omeprazole can be used in the treatment of GERD and peptic ulcer disease. However, the safety and efficacy for long-term use have not been established.
- **Geriatric Use:**
 - No dose adjustment is necessary, but caution is recommended for elderly patients due to the increased risk of bone fractures, kidney disease, and hypomagnesemia.

8. Overdose:

- Symptoms of overdose may include confusion, dizziness, blurred vision, and tachycardia.
- In case of overdose, symptomatic treatment is recommended, and immediate medical consultation should be sought.

9. Storage and Handling:

- **Storage:** Store at room temperature (15-30°C, 59-86°F). Protect from moisture and keep the bottle tightly closed.

- **Handling: Keep out of reach of children. Do not use after the expiration date on the package.**

Packaging:

- **Each Alu-Alu strip of Gerzole-40 contains 10 Capsules.**
- **Each box of Gerzole-40 contains 10 strips.**

Note: This summary provides general prescribing information.