

# Bold

Capsules\*

بولڈ کپسولز

## COMPOSITION:

Each capsule contains: Omeprazole Pellets\* eq. to Omeprazole Activity..20 & 40 mg respectively.

**DESCRIPTION:** Omeprazole belongs to a new class of anti-secretory compounds, the substituted benzimidazoles that suppress gastric acid secretion. Substituted benzimidazole, 5-methoxy-2-[[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]Sulfinyl]-1H-benzimidazole. A compound that inhibits gastric acid secretion. Its empirical formula is C<sub>17</sub>H<sub>19</sub>N<sub>3</sub>O<sub>3</sub>S, with a molecular weight of 345.42. It is available in pellet form.

**PHARMACOLOGY:** Absorption is rapid, with peak plasma levels of Omeprazole occurring within 0.5 to 3.5 hours. Absolute bioavailability is about 30-40% at doses of 20-40 mg, due in large part to presystemic metabolism. The plasma half-life is 0.5 to 1 hour. Protein binding is approximately 95%. Omeprazole is completely metabolized by the liver. The majority of the dose (about 77%) is eliminated in urine as at least 6 metabolites. The remainder of the dose is recovered in feces.

**INDICATIONS:** *Duodenal Ulcer:* BOLD Capsules are indicated for short-term treatment of active duodenal ulcer. Most patients heal within 4 weeks. In combination with clarithromycin and amoxicillin, BOLD Capsules are indicated for the treatment of patients with *H. pylori* infection and duodenal ulcer disease to eradicate *H. pylori*. *Gastric Ulcer:* BOLD Capsules are recommended for short-term treatment (4-8 weeks) of active benign gastric ulcer. *Treatment of Gastroesophageal Reflux Disease (GERD):* Symptomatic GERD: BOLD Capsules are indicated for the treatment of heartburn and other symptoms associated with GERD. Erosive Esophagitis: BOLD Capsules are recommended for the short-term treatment (4-8 weeks) of erosive esophagitis, which has been diagnosed by endoscopy. *Maintenance of Healing of Erosive Esophagitis:* BOLD Capsules are indicated to maintain healing of erosive esophagitis. *Pathological Hypersecretory Conditions:* BOLD Capsules are recommended for the long-term treatment of pathological hypersecretory conditions (e.g., Zollinger-Ellison syndrome, multiple endocrine adenomas and systemic mastocytosis).

**CONTRAINDICATIONS:** Omeprazole is contraindicated in patients with known hypersensitivity to any component of the formulation.

**POSSIBLE ADVERSE EFFECTS:** Omeprazole is generally well tolerated. The commonest adverse effects encountered are headache, diarrhea, abdominal pain, nausea and vomiting.

**DRUG INTERACTIONS:** Omeprazole can prolong the elimination of drugs (e.g., diazepam, warfarin and phenytoin) that are metabolized by oxidation in the liver. There have been reports of increased INR and prothrombin time in patients receiving proton pump inhibitors, including Omeprazole and warfarin concomitantly. Drugs metabolized via the cytochrome P450 system (e.g., cyclosporine, disulfiram and benzodiazepines) have interacted with Omeprazole. Omeprazole may interfere with the absorption of drugs where gastric pH is an important determinant of their bioavailability (e.g., ketoconazole, ampicillin esters and iron salts).

**WARNINGS:** *General:* Symptomatic response to therapy with Omeprazole does not preclude the presence of gastric malignancy. Atrophic gastritis has been noted occasionally in gastric corpus biopsies

from patients treated long-term with Omeprazole. **Pregnancy:** Omeprazole should be used during pregnancy only if the potential benefit to the pregnant woman justifies the potential risk to the fetus. **Lactation:** Because Omeprazole is excreted in human milk, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. **Pediatric Use:** The safety and effectiveness of Omeprazole have not been established for pediatric patients less than 2 years of age.

**DOSAGE & ADMINISTRATION:** *Short-Term Treatment of Active Duodenal Ulcer:* Adult oral dose of BOLD is 20 mg once-daily. Most patients heal within 4 weeks. Some patients may require an additional 4 weeks of therapy. *H. pylori Eradication for the Reduction of the Risk of Duodenal Ulcer Recurrence: Triple Therapy (Omeprazole/ Clarithromycin/Amoxicillin):* The recommended adult oral regimen is BOLD 20 mg plus clarithromycin 500 mg plus amoxicillin 1000 mg each given twice-daily for 10 days. An additional 18 days of BOLD 20 mg once-daily is recommended for ulcer healing and symptom relief. *Dual Therapy (Omeprazole/ Clarithromycin):* The recommended adult oral regimen is BOLD 40 mg once-daily plus clarithromycin 500 mg thrice-daily for 14 days. An additional 14 days of BOLD 20 mg once-daily is recommended for ulcer healing and symptom relief. *Gastric Ulcer:* The recommended adult oral dose is 40 mg 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 20 mg daily for up to 4 weeks. The recommended adult oral dose for the treatment of patients with erosive esophagitis and accompanying symptoms due to GERD is 20 mg daily for 4 to 8 weeks. *Maintenance of Healing of Erosive Esophagitis:* The recommended adult oral dose is 20 mg daily. *Pathological Hypersecretory Conditions:* The recommended adult oral starting dose is 60 mg once a day. Doses should be adjusted to individual patient needs and should continue for as long as clinically indicated. Doses up to 120 mg thrice-daily have been administered. Daily dosages of greater than 80 mg should be administered in divided doses. No dosage adjustment is necessary in the elderly.

**SPECIAL INSTRUCTIONS TO THE PHYSICIAN:** **Overdosage:** 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.

**STORAGE / PRECAUTIONS:** Store in a cool, dry and dark place below 25 °C. Keep all medicines out of the children's reach.

**PRESENTATION:** BOLD 20 & 40 mg capsules are available in Alu-Alu packing containing 14 capsules, respectively.

\*Scotmann Specs.

عمومی خوراک: ڈاکٹر کی ہدایت کے مطابق - احتیاط: دوا صرف مستند ڈاکٹر کے زیر ہدایت استعمال کریں۔ روشنی، نمی اور گرمی سے بچائیں۔  
25 ڈگری سینٹی گریڈ سے کم درجہ حرارت پر محفوظ کریں۔ تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

Complete Medical Information available only for doctors on request.



Manufactured by: **SCOTMANN PHARMACEUTICALS**

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www.scotmann.com