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Prilosec

(Omeprazole) - AstraZeneca

THERAPEUTIC CLASS
Proton pump inhibitor

DEA CLASS
RX

INDICATIONS
Short-term treatment of active duodenal ulcer (DU) and active benign gastric ulcer (GU) in adults. Treatment of heartburn and other symptoms associated with gastroesophageal reflux disease (GERD) in adults and pediatric patients. Short-term treatment and maintenance of healing of erosive esophagitis (EE) in adults and pediatric patients. Long-term treatment of pathological hypersecretory conditions (eg, Zollinger-Ellison syndrome, multiple endocrine adenomas, systemic mastocytosis) in adults. Combination therapy with clarithromycin +/- amoxicillin in *Helicobacter pylori* infection and DU disease for *H. pylori* eradication in adults.

ADULT DOSAGE
Adults: Take ac. Active DU: 20mg qd for 4-8 weeks. GERD: Without Esophageal Lesions: 20mg qd for up to 4 weeks. With EE and Accompanying Symptoms: 20mg qd for 4-8 weeks. May give an additional 4 weeks of treatment if no response after 8 weeks. Consider additional 4-8 week courses if there is recurrence of symptoms/EE. GU: 40mg qd for 4-8 weeks. Maintenance of Healing of EE: 20mg qd. Consider dose reduction with hepatic impairment or in Asian population. Hypersecretory Conditions: Initial: 60mg qd. Titrate: Adjust to individual needs and continue for as long as clinically indicated. Doses up to 120mg tid have been administered. Give >80mg/day in divided doses. *H. pylori* Eradication: Triple Therapy: 20mg + clarithromycin 500mg + amoxicillin 1000mg, each given bid for 10 days. Give additional 18 days of omeprazole 20mg qd if ulcer is present at the time of initiation of therapy. Dual Therapy: 40mg qd + clarithromycin 500mg tid for 14 days. Give additional 14 days of omeprazole 20mg qd if ulcer is present at the time of initiation of therapy.

PEDIATRIC DOSAGE
Pediatrics: 1-16 Yrs: Take ac. GERD/Maintenance of Healing of EE: ≥20kg: 20mg/day. 10-<20kg: 10mg/day. 5-<10kg: 5mg/day.

HOW SUPPLIED
Cap, Delayed-Release: 10mg, 20mg, 40mg; Sus, Delayed-Release: (Magnesium) 2.5mg, 10mg (granules/pkt)

WARNINGS/PRECAUTIONS
Symptomatic response does not preclude the presence of gastric malignancy. Atrophic gastritis reported with long-term use. May increase risk of *Clostridium difficile*-associated diarrhea (CDAD), especially in hospitalized patients. May increase risk for osteoporosis-related fractures of the hip, wrist, or spine, especially with high-dose and long-term therapy. Use lowest dose and shortest duration appropriate to the condition being treated. Hypomagnesemia reported and may require Mg^{2+} replacement and discontinuation of therapy; consider monitoring Mg^{2+} levels prior to and periodically during therapy with prolonged treatment. Drug-induced decrease in gastric acidity results in enterochromaffin-like cell hyperplasia and increased chromogranin A (CgA) levels, which may interfere with investigations for neuroendocrine tumors; temporarily d/c treatment before assessing CgA levels.

ADVERSE REACTIONS
Headache, diarrhea, abdominal pain, N/V, flatulence.

DRUG INTERACTIONS
May reduce atazanavir and nelfinavir levels; concomitant use not recommended. May change absorption or levels of antiretrovirals. May interfere with absorption of drugs where gastric pH is an important determinant of bioavailability (eg, ketoconazole, ampicillin esters, iron salts, erlotinib, digoxin). May prolong elimination of drugs metabolized by oxidation in the liver (eg, diazepam, warfarin, and phenytoin). Monitor patients taking drugs metabolized by CYP450 (eg, cyclosporine, disulfiram, benzodiazepines). Monitor for increases in INR and PT with warfarin. Voriconazole (a combined inhibitor of CYP2C19 and CYP3A4) may increase levels. Decreased levels with CYP2C19 or CYP3A4 inducers; avoid with St. John's wort or rifampin. Reduces pharmacological activity of clopidogrel; avoid concomitant use. May increase levels of saquinavir, cilostazol, and tacrolimus; consider saquinavir and cilostazol dose reduction. Caution with digoxin or other drugs that may cause hypomagnesemia (eg, diuretics). May elevate and prolong levels of methotrexate (MTX) and/or its metabolite, possibly leading to toxicities; consider temporary withdrawal of therapy with high-dose MTX.

PREGNANCY
Category C, caution in nursing.

MECHANISM OF ACTION
Proton pump inhibitor; suppresses gastric acid secretion by specific inhibition of the H^+/K^+ ATPase enzyme system at the secretory surface of the gastric parietal cell.

PHARMACOKINETICS

Absorption: (Cap) Rapid. Absolute bioavailability (30-40%); T_{max}=0.5-3.5 hrs. **Distribution:** Plasma protein binding (95%); found in breast milk. **Metabolism:** Extensive via CYP450. **Elimination:** Urine (77%), feces; (Cap) $T_{1/2}$=0.5-1 hr.

ASSESSMENT

Assess for hypersensitivity to the drug, risk for osteoporosis-related fractures, hepatic impairment, pregnancy/nursing status, and possible drug interactions. Obtain baseline Mg^{2+} levels.

MONITORING

Monitor for signs/symptoms of atrophic gastritis, bone fractures, hypersensitivity reactions, CDAD, and other adverse reactions. Monitor INR and PT when given with warfarin. Monitor Mg^{2+} levels periodically.

PATIENT COUNSELING

Advise to immediately report and seek care for diarrhea that does not improve and for any cardiovascular/neurological symptoms, including palpitations, dizziness, seizures, and tetany. Inform of alternative administration options if patient has difficulty swallowing.

ADMINISTRATION/STORAGE

Administration: Oral route. (Cap) Swallow whole or, alternatively, open cap and sprinkle all pellets on 1 tbsp of applesauce, then swallow immediately with a glass of cool water; do not chew or crush the pellets. (Sus) May be given via gastric/NG route. Refer to PI for administration instructions. **Storage:** (Cap) 15-30°C (59-86°F). Protect from light and moisture. (Sus) 25°C (77°F); excursions permitted to 15-30°C (59-86°F).