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Prilosec OTC Offers Exceptional Value for PPI Therapy

By Dean Haxby, Pharm.D., OSU College of Pharmacy

Prilosec OTC was approved by the FDA in June 2003 and is the first proton pump inhibitor (PPI) available in the U.S. for over-the-counter (OTC) treatment of frequent heartburn (1). While much attention has been focused on the availability of this product for self-treatment, the another important benefit is that it provides clinicians with a low-cost option for one of the most commonly prescribed, and top expenditure drug classes. For every patient on chronic PPI therapy converted to Prilosec OTC, the savings would range from approximately \$872-\$1208 per year. Therefore, prescribing Prilosec OTC as an alternative to other PPIs is an important opportunity for clinicians to help stretch the limited resources of the Oregon Health Plan.

Differences Between Prilosec and Prilosec OTC

Prescription (Rx) omeprazole is a capsule formulation containing enteric-coated granules of omeprazole base, whereas Prilosec OTC is a tablet containing omeprazole magnesium in an enteric-coated multiple-unit pellet system (MUPS). Prilosec OTC contains 20.6 mg of omeprazole magnesium, which provides 20mg of omeprazole base. The omeprazole magnesium salt allows the formulation and manufacture of tablets that are more tamper-resistant than capsules, which is an important consideration in the OTC setting (2). While Rx omeprazole (Prilosec) and Prilosec OTC produce nearly identical blood levels of omeprazole base and equivalent therapeutic effects, a pharmacist may not substitute one for the other. **Thus it is important to specify "Prilosec OTC" or "omeprazole magnesium" on the prescription.**

Role of Prilosec OTC in Self-treatment

In two pivotal studies submitted to the FDA, Prilosec OTC once-daily for 14 days was more effective than placebo in patients with frequent heartburn (1). Within 5 days of stopping treatment, there was no significant difference in symptoms compared to the control group. It is recommended that therapy not be used for more than 14 days in any four-month period without consulting a clinician. Therefore, the role of self-treatment is limited.

Role of Prilosec OTC in Clinician Directed Care

The same formulation of omeprazole used for Prilosec OTC is available in 31 other countries, commonly under the brand name Losec MUPS (2). Losec MUPS carries similar indications in other countries as Rx Prilosec in the US. For example, in the United Kingdom, Losec MUPS is indicated for esophageal reflux disease, duodenal ulcers, gastric ulcers, NSAID-induced ulcers, *H. pylori* eradication, dyspepsia, prophylaxis of acid aspiration and Zollinger-Ellison Syndrome (3).

An evidence-based review of the PPI drug class conducted by the Oregon Evidence-based Practice Center under the guidance of the PPI Subcommittee of the Oregon Health Resources Commission concluded **there is no clinical difference among the various PPIs in terms of efficacy or safety** (4). As the lowest cost option in the PPI class, Prilosec OTC has been added to the Oregon Practitioner Managed Preferred Drug List (5).

Adverse Effects

The adverse effect profile of Prilosec OTC is similar to other PPIs. This formulation of omeprazole has established an extensive safety profile based on use abroad (6). Prilosec OTC, like the prescription product, is well tolerated with headache, diarrhea, nausea, abdominal pain or rash occurring in 1%-5% of patients. Both omeprazole formulations may increase levels of drugs metabolized by CYP-2C19, such as warfarin and phenytoin. Drugs requiring acid for absorption (e.g. itraconazole) also may be affected.

Cost

While one PPI does not offer a clinical advantage over another, Prilosec OTC has a dramatic price advantage. Approximately five patients can be treated with Prilosec OTC for the cost of treating one patient with a different PPI. If 90% of the current open-card Medicaid PPI users were converted to Prilosec OTC, the state would save over \$3,000,000 in one year.

| Generic | Brand | Dose | Annual Cost \$* |
|-----------------|--------------|-------------------|-----------------|
| Omeprazole mag. | Prilosec OTC | 20.6 mg qd | 193 |
| Omeprazole | Generic (Rx) | 20 mg qd | 1065 |
| Pantoprazole | Protonix | 40 mg qd | 1065 |
| Rabeprazole | Aciphex | 20 mg qd | 1309 |
| Esomeprazole | Nexium | 20 mg or 40 mg qd | 1343 |
| Lansoprazole | Prevacid | 30 mg qd | 1401 |

* AWP – 15% based on Redbook Update August 2003 or the OHP maximum allowable cost for generic omeprazole.

Administration

The adult dose of Prilosec OTC is the same as Rx omeprazole, typically one tablet (20.6 mg) daily. The tablets may be dispersed in water, juice or yogurt for patients with difficulty swallowing tablets. Once dispersed, the drug can be suspended with gentle mixing and the entire mixture is consumed. Because the pellets themselves are enteric-coated, they will not be dissolved in the acidic medium of the stomach. However, it is important that the tablets not be crushed or chewed which would compromise the enter-coating.

Summary

Clinicians should prescribe Prilosec OTC as the preferred first line agent for PPI therapy. It offers comparable clinical performance as other PPIs at a fraction of the cost.

Reviewers: Michele Koder, Pharm.D. OSU College of Pharmacy; David Labby, MD, CareOregon; and Marian McDonagh, Pharm.D. OHSU Evidence-based Practice Center.

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