

**NEW DRUG
APPROVAL**

Prilosec[™] OTC (omeprazole)

Prilosec[™] OTC (omeprazole, Proctor & Gamble) was approved in June 2003 by the United States (US) Food and Drug Administration (FDA) for the treatment of frequent heartburn that occurs two or more times per week for people ages 18 years or over. It is the first over-the-counter (OTC) treatment for frequent, but not chronic, heartburn available at full prescription strength and that lasts up to 24 hours. Heartburn occurs when small amounts of stomach acid rise up into the esophagus, which is the tube that carries food from the mouth to the stomach, and causes the feeling of burning in the chest. Prilosec OTC belongs to a class of drugs known as proton pump inhibitors (PPIs). This class of drugs reduces stomach acid by blocking acid pumps in the stomach, thereby relieving heartburn. The FDA approved dose for Prilosec OTC is 20mg before eating once daily for 14 days for frequent heartburn. Other prescription strengths of Prilosec are not available OTC. Prilosec OTC should not be taken for more than 14 days or more often than one 14-day course every four months unless directed by a doctor. If symptoms persist or worsen, the participant should contact their physician for further evaluation. Prilosec OTC is expected to cost about \$1 per tablet. Anticipated availability of the OTC product is September 2003.

BACKGROUND

More than 60 million Americans experience heartburn at least once a month and more than 15 million Americans experience heartburn symptoms each day. Prilosec OTC will join the other OTC products available for the treatment of heartburn, such as Pepcid AC[®] and Zantac75[®]. Prilosec OTC has very limited use without a prescription and physician monitoring. The specific indication of a 14-day regimen once every four months for Prilosec OTC limits the number of people who should use this medication without physician supervision. People with chronic heartburn will need to use a longer course of therapy and may require higher doses that would require use of prescription medication.

**CAREMARK
RESPONSE**

- In general, Caremark recommends continued coverage for Prilosec and other proton pump inhibitors (PPIs) after the launch of Prilosec OTC given the narrow approved indication for the OTC product, and the single dosage strength available.
- More selective management can be achieved by excluding coverage for Prilosec 20 mg for 14 days or less.
- For those clients with CustomCare Mail and/or CustomCare Retail, an OTC option will be recommended where clinically appropriate.

CONTACT

For more information call your Caremark account representative.

Please Note: This document provides a brief overview of the subject. Please refer to the manufacturer's full prescribing information for a complete discussion of the product. This review is provided as a reference only, and is based in part on information derived from third parties.