

TrendsRx® Rx-to-OTC and Generic Update

OTC: Prevacid® 24 HR (lansoprazole)

Generic: lansoprazole (Prevacid®)*

Drug Approval

- Prescription Prevacid® (lansoprazole, Takeda Pharmaceuticals North America, Inc.) is approved by the FDA for:
 - the short-term treatment of gastroesophageal reflux disease (GERD), erosive esophagitis, active benign gastric ulcer and active duodenal ulcer;
 - the treatment of *Helicobacter pylori* infection and duodenal ulcer disease (with antibiotic therapy), non-steroidal anti-inflammatory drug (NSAID) associated gastric ulcer, and Zollinger-Ellison syndrome;
 - the maintenance of healed duodenal ulcers and erosive esophagitis; and
 - the risk reduction of NSAID-associated gastric ulcer.
- On May 18, 2009, Novartis Consumer Health Inc. received approval from the FDA to market over-the-counter (OTC) Prevacid® 24 HR, in 15 mg strength. The OTC version is indicated only for the treatment of frequent heartburn that occurs two or more days per week.
- Prevacid® 24 HR will be the first OTC proton pump inhibitor (PPI) introduced into the U.S. market since Prilosec OTC was approved in 2003.
- On May 23, 2008, the FDA granted Teva Pharmaceutical Industries Ltd. tentative approval for a prescription generic version of Prevacid in both the 15 mg and 30 mg strengths. Other manufacturers may also receive approval to market the generic version. Final approvals are expected to be granted in November 2009.

Therapeutic Class

- Proton Pump Inhibitors

United States Industry Brand Sales†

- \$3.3 Billion

Anticipated OTC Dosage Form and Strength

- Capsules, delayed-release; 15 mg

Anticipated Generic Dosage Form and Strengths

- Capsules, delayed-release; 15 mg and 30 mg

Anticipated Launch Date[‡]

- OTC: November 12, 2009
- Generic: November 24, 2009

Selected Medications Available in the Class[§]

- OTC: Prilosec OTC®, omeprazole magnesium
- Generics (various manufacturers): pantoprazole sodium, **omeprazole**
- Brands: **Kapidex™** (dexlansoprazole, Takeda Pharmaceuticals North America, Inc.); **Nexium®** (esomeprazole, AstraZeneca); Prilosec® (omeprazole magnesium, AstraZeneca); Zegerid® (omeprazole/sodium bicarbonate, Santarus Inc.); Aciphex® (rabeprazole, Eisai Inc.); Protonix® (pantoprazole, Wyeth Pharmaceuticals Inc.)

Benefit Design Options^¹

- Currently, CVS Caremark is developing plan design models to assess cost and member impact for various strategies.
- CVS Caremark will offer the OTC Connect® program to assist clients and plan participants with the transition from prescription to OTC products. The program includes letters sent directly to plan participants informing them of the status change from prescription to OTC, when the product will be available on shelves, and which dosage forms will be available. For additional savings, a high-value coupon for Prevacid® 24 HR will also be included in the mailings.

CVS Caremark Response

- CVS Caremark recognizes the unique needs of plan participants with GERD.
- CVS Caremark is committed to assisting clients develop appropriate management strategies for OTC and generic drugs.
- CVS Caremark offers publications and Web-based applications to ensure that our clients receive timely information regarding generic options. In addition, many CVS Caremark physician- and plan participant-targeted offerings are also available to help both clients and plan participants realize the significant cost savings that generic medications offer.
- **Additional communications regarding the status of Prevacid will be sent as new information becomes available.**
- **For more information on enrolling in the OTC Connect program, contact your CVS Caremark account representative.**

Rx=prescription; OTC=over the counter

Please Note: This document provides a brief overview of the subject. This review is provided as a reference only and is based in part on information derived from third parties.

* This information is current as of September 3, 2009. The information presented is subject to change and is represented to the best of our knowledge at the time of this publication.

† Industry sales data from the last 12 months.

‡ A launch date may not reflect the actual availability of this medication. Due to circumstances beyond the control of CVS Caremark, information related to prospective medication launch dates is subject to change without notice. This information should not be solely relied upon for decision-making purposes. This medication is expected to be available for purchase within a few days of launch.

§ Bolded medicines are currently on the CVS Caremark Performance Drug List and CVS Caremark Primary/Preferred Drug List

¶ Changes in coverage for the PPI class may have potential rebate impacts. Please consult your CVS Caremark account representative to determine what rebate impacts such changes in coverage of the PPI class may have for you.

This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

References

- CVS Caremark Internal Pharmacy Budget Impact, Research and Development.
- Drugs@FDA. Rockville, MD: Food and Drug Administration, Center for Drug Evaluation and Research. <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>. Accessed August 17, 2009.
- Facts & Comparisons. Facts & Comparisons Web site. <http://www.factsandcomparisons.com/>. Accessed August 17, 2009.
- Prevacid Prescribing Information. Deerfield, IL: Takeda Pharmaceuticals North America, Inc, July 31, 2009.
- Novartis receives approval from FDA to market Prevacid®24HR as first and only OTC proton pump inhibitor in original formulation [press release]. Basel, Switzerland: Novartis AG; May 14, 2009. <http://www.novartis.com/newsroom/media-releases/en/2009/1314777.shtml>. Accessed August 12, 2009.
- Teva announces tentative approval of generic Prevacid® Delayed-Release Capsules [press release]. Reuters. Jan 23, 2008. <http://www.reuters.com/article/pressRelease/idUS178366+23-Jan-2008+BW20080123>. Accessed August 17, 2009.