AMERICAN HEALTH CARE

DRUG PRODUCTS & SAFETY NEWS

Prilosec Expanded Indication

February 17, 2016

The U.S. Food and Drug Administration (FDA) has approved an expanded indication for AstraZeneca's PriLOSEC (omeprazole) delayed-release capsules and oral suspension. Indications and usage now includes short-term treatment (up to 6 weeks) of erosive esophagitis (EE) due to acid-mediated gastroesophageal reflux disease (GERD) in pediatric patients 1 month to less than 1 year of age.

PriLOSEC was previously approved for the treatment of EE due to acid-mediated GERD in patients 1 year and older. PriLOSEC is also indicated for treatment of active duodenal ulcer in adults, for eradication of Helicobacter pylori to reduce the risk of duodenal ulcer recurrence in adults, for treatment of active benign gastric ulcer in adults, for treatment of symptomatic GERD in patients 1 year of age and older, for maintenance of healing of EE due to acid-mediated GERD in patients 1 year of age and older, and for pathological hypersecretory conditions in adults.

Healthcare professionals and patients are encouraged to report any adverse events or side effects related to the use of this product and/or quality problems to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- ✓Complete and submit the report online: www.fda.gov/MedWatch/report.htm
- ✓Complete and return a form by mail (address on the pre-addressed form) or fax (1-800-FDA-0178).

[Call 1-800-332-1088 to request a reporting form or download a form at http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm.]

Source: Facts and Comparisons

Additional information: http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022056s018lbl.pdf

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