Proton Pump Inhibitor drugs (PPIs): Drug Safety Communication - Low Magnesium Levels Can Be Associated With Long-Term Use

U.S. Food & Drug Administration

Over-the-counter (OTC) PPIs include Prilosec OTC (omeprazole), Zegerid OTC (omeprazole and sodium bicarbonate), and Prevacid 24HR (lansoprazole).

AUDIENCE: Consumer, Gastroenterology, Family Practice

ISSUE: FDA notified healthcare professionals and the public that prescription proton pump inhibitor (PPI) drugs may cause low serum magnesium levels (hypomagnesemia) if taken for prolonged periods of time (in most cases, longer than one year). Low serum magnesium levels can result in serious adverse events including muscle spasm (tetany), irregular heartbeat (arrhythmias), and convulsions (seizures); however, patients do not always have these symptoms. Treatment of hypomagnesemia generally requires magnesium supplements. In approximately one-quarter of the cases reviewed, magnesium supplementation alone did not improve low serum magnesium levels and the PPI had to be discontinued.

BACKGROUND: PPIs work by reducing the amount of acid in the stomach and are used to treat conditions such as gastroesophageal reflux disease (GERD), stomach and small intestine ulcers, and inflammation of the esophagus.

RECOMMENDATION: Healthcare professionals should consider obtaining serum magnesium levels prior to initiation of prescription PPI treatment in patients expected to be on these drugs for long periods of time, as well as patients who take PPIs with medications such as digoxin, diuretics or drugs that may cause hypomagnesemia. For patients taking digoxin, a heart medicine, this is especially important because low magnesium can increase the likelihood of serious side effects. Healthcare professionals should consider obtaining magnesium levels periodically in these patients. For additional information, refer to the Data Summary section of the FDA Drug Safety Communication.

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

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm

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- Download form [2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[03/02/2011 - Drug Safety Communication [3] - FDA]

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[1] http://www.fda.gov/MedWatch/report.htm
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