Proton Pump Inhibitors (PPIs) - Drug Safety Communication: Clostridum Difficile-Associated Diarrhea (CDAD) Can be Associated With Stomach Acid Drugs

U.S. Food & Drug Administration

AUDIENCE: Gastroenerology, Family Practice, Consumer

ISSUE: FDA notified the public that the use of stomach acid drugs known as proton pump inhibitors (PPIs) may be associated with an increased risk of Clostridium difficile–associated diarrhea (CDAD). A diagnosis of CDAD should be considered for patients taking PPIs who develop diarrhea that does not improve. The FDA is working with manufacturers to include information about the increased risk of CDAD with use of PPIs in the drug labels.

FDA is also reviewing the risk of CDAD in users of histamine H2 receptor blockers. H2 receptor blockers are used to treat conditions such as gastroesophageal reflux disease (GERD), stomach and small intestine ulcers, and heartburn.

BACKGROUND: Proton pump inhibitors (PPIs) are marketed under various brand and generic drug names as prescription and over-the-counter (OTC) products. They work by reducing the amount of acid in the stomach. Prescription PPIs are used to treat conditions such as gastroesophageal reflux disease (GERD), stomach and small intestine ulcers, and inflammation of the esophagus. Over-the-counter PPIs are used to treat frequent heartburn.

Clostridium difficile (C. difficile) is a bacterium that can cause diarrhea that does not improve. Symptoms include watery stool, abdominal pain, and fever, and patients may go on to develop more serious intestinal conditions. The disease can also be spread in hospitals.

RECOMMENDATION: Patients should immediately contact their healthcare professional and seek care if they take PPIs and develop diarrhea that does not improve. Information for Healthcare Professionals:

- A diagnosis of CDAD should be considered for PPI users with diarrhea that does not improve.
- Advise patients to seek immediate care from a healthcare professional if they experience watery stool that does not go away, abdominal pain, and fever while taking PPIs.

- Patients should use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated.

Healthcare professionals and patients are encouraged to report adverse events or side effects 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 [1]
- 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

[02/08/2012 - Drug Safety Communication [3] - FDA]

SOURCE [4]

Source URL (retrieved on *04/02/2015 - 6:46am*):
http://www.mdtmag.com/news/2012/02/proton-pump-inhibitors-ppis-drug-safety-communication-clostridum-difficile-associated-diarrhea-cdad-can-be-associated-stomach-acid-drugs?qt-recent_content=0

Links:
[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
[3] http://www.fda.gov/Drugs/DrugSafety/ucm290510.htm
[4] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm290838.htm