FDA Issues Warning on Acid Reflux Drugs

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3 comment(s)

The FDA warned today that use of proton pump inhibitors (PPIs) -- including popular brands such as Nexium, Prilosec, and Prevacid -- may increase the risk of Clostridium difficile-associated diarrhea.

The warning comes after a review of data from the agency's Adverse Event Reporting System and the medical literature suggested such a link. A meta-analysis reported at the 2010 meeting of the American College of Gastroenterology yielded the same finding.

Many of the adverse event reports involved patients who were elderly, had underlying medical conditions, or were taking broad spectrum antibiotics. All of those factors could have contributed to the greater risk of *C. difficile*-associated diarrhea, but the use of PPIs could not be excluded.

The FDA advised healthcare providers to consider a diagnosis of *C. difficile*-associated diarrhea if patients taking PPIs present with diarrhea that is not improving and said patients should take the lowest dose of PPI for the shortest time possible to improve the condition being treated.

The agency is working with the drug makers to modify the labels to include the possible risk of *C. difficile*-associated diarrhea.

The warning applies to the following PPIs, both prescription and over-the-counter:

- rabeprazole sodium (AcipHex)
- dexlansoprazole (Dexilant)
- esomeprazole magnesium (Nexium)
- omeprazole OTC
- lansoprazole (Prevacid) and Prevacid 24hr OTC
- omeprazole (Prilosec) and Prilosec OTC
- pantoprazole sodium (Protonix)
- esomeprazole magnesium and naproxen (Vimovo)
- omeprazole and sodium bicarbonate (Zegerid) and Zegerid OTC

PPIs have been associated with other adverse events in the past, including resistance to clopidogrel (Plavix), low magnesium levels resulting in a greater risk of leg spasms, arrhythmias, and seizures, greater risk of osteoporotic fractures from chronic use, and cardiac birth defects when used during pregnancy.

The FDA is also reviewing the possible risk of in *C. difficile*-associated diarrhea in users of another class of acid suppressing medications, the histamine H_2 receptor blockers.

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