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Proton-Pump Inhibitors May Predispose Patients to Bacterial Diarrhea

NOTICE

On February 8, 2012, the Food and Drug Administration released a public health advisory indicating that the use of certain gastric acid suppression medications known as Proton Pump Inhibitors (PPI's) may lead to an increased risk for developing Clostridium difficile-associated diarrhea (CDAD).

BACKGROUND

Proton pump inhibitors are a popular gastric acid suppression agent available in both over-the-counter (OTC) and prescription formulations. Reducing the amount of acid produced in the stomach, PPI's are commonly used for the treatment and prevention of gastrointestinal conditions such as gastroesophageal reflux disease (GERD), gastric/intestinal ulcers, and for the prevention of gastritis caused by the use of non-steroidal anti-inflammatory drugs (NSAIDs). After reviewing adverse event reporting data, the FDA indicates that there may be a correlation between the use of certain gastric acid suppressants and the development of diarrhea caused by clostridium difficile, a bacterium common in hospital settings and in the elderly. While some clinical studies have indicated a possible relationship between the development of diarrhea and the use of PPI's, the FDA indicates that this concern may also extend to other gastric acid suppression agents known as H₂ receptor blockers (i.e. Zantac[®], Pepcid[®], etc); although, data is not conclusive.

The following list represents the current PPI's available in the U.S. market, either as mono-products or in combination with other medications.

- AcipHex[®] (rabeprazole)
- Dexilant[®] (dexlansoprazole)
- Nexium[®] (esomeprazole)
- Prilosec[®] (omeprazole)
- Prevacid[®] (lansoprazole)
- Protonix[®] (pantoprazole)
- Vimovo[®] (esomeprazole/naproxen)
- Zegerid[®] (omeprazole/sodium bicarbonate)

RECOMMENDED ACTIONS

Due to the non-conclusive nature of the FDA's alert, there is no recommended action necessary at this time. The FDA is working closely with product manufacturers to include information regarding the risk for CDAD in the product label for proton pump inhibitors.

Reference: Proton Pump Inhibitors (PPIs) – Drug Safety Communication: Clostridium Difficile-Associated Diarrhea (CDAD) Can be Associated with Stomach Acid Drugs. FDA MedWatch. <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm290838.htm> <Accessed February 8,

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