



**The FDA Safety Information and  
Adverse Event Reporting Program**

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

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

[Posted 02/08/2012]

FDA 公告，使用 PPIs 類的胃藥可能造成 Clostridium difficile-associated diarrhea (CDAD) 的風險增加。診斷為 CAPD 且腹瀉情形一直沒有改善的病人，應考慮 PPIs 類藥物造成腹瀉的可能性。FDA 與製造廠商會在藥品仿單加註相關訊息。FDA 目前正在評估 H2 receptor blockers 是否會造成 CAPD。

使用 PPIs 類藥物且一直有腹瀉情形的患者，應立即告知醫護人員；醫護人員應了解下列信息：

- 使用 PPIs 類的藥物且持續有腹瀉情形的患者，應考慮 CDAD 的可能性。
- 若病人正在使用 PPIs 類的藥物，應告知病人若有持續的腹瀉、像水一樣的大便、腹痛、發燒，須主動告訴醫護人員。
- 病人使用 PPIs 類的藥物時，應使用最低劑量和最短的療程。

[Updated 02/08/2012]

**AUDIENCE:** Gastroenterology, 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.

H<sub>2</sub> 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.