

# FDA Warns of Fracture Risk With Popular Heartburn Drugs

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TUESDAY, May 25 (HealthDay News) -- Blockbuster heartburn medications such as Prevacid, Prilosec and Nexium will now carry a warning on their labels linking the drugs to a heightened risk for fractures, the U.S. Food and Drug Administration announced late Tuesday.

The label will advise consumers to use this class of medicines, called proton pump inhibitors (PPIs), carefully, because high doses have been associated with an increased risk of fractures of the hip, wrist and spine, the agency said.

PPIs, which include prescription and over-the-counter drugs, work by blocking stomach acid from being produced. However, as with any drug, this benefit comes with some risk, the FDA said.

"Epidemiology studies suggest a possible increased risk of bone fractures with the use of proton pump inhibitors for one year or longer, or at high doses," Dr. Joyce Korvick, deputy director for safety in FDA's Division of Gastroenterology Products, said in an agency statement.

"Because these products are used by a great number of people, it's important for the public to be aware of this possible increased risk and, when prescribing proton pump inhibitors, health care professionals should consider whether a lower dose or shorter duration of therapy would adequately treat the patient's condition," she said. Based on a review of the scientific evidence, the agency is instructing the makers of the drugs to change the labels for both the prescription and the over-the-counter versions of the proton pump inhibitors. The FDA based its decision on the results of seven studies, six of which noted a link between PPIs and fracture, primarily among users aged 50 and over.

Proton pump inhibitors include the drugs esomeprazole (Nexium), dexlansoprazole (Dexilant), omeprazole (Prilosec, Zegerid), lansoprazole (Prevacid), pantoprazole (Protonix), and rabeprazole (Aciphex). These medicines are used to treat gastroesophageal reflux disease (GERD), stomach and small intestine ulcers and inflammation of the esophagus. Over-the-counter versions of Prevacid, Prilosec and Zegerid also fall into this class of drugs.

The FDA is advising consumers to not stop taking PPIs until they have consulted with their doctor. However, patients should be aware of the increased risk for fractures. The highest risk was seen in people taking higher doses of PPIs, or among those who took them for a year or more, the agency said.

For people taking over-the-counter proton pump inhibitors, the FDA said they should only be taken for 14 days to help ease frequent heartburn. If heartburn continues, people should see their doctor. Under no circumstances should over-the-counter PPIs be taken for more than three 14-day periods in a year, the agency said.

Dr. Amar R. Deshpande, an assistant professor of gastroenterology at the University of Miami Miller School of Medicine, said the data behind the FDA decision "is not new."

PPIs may disrupt the body's ability to absorb calcium, which, in turn, can increase the risk for fractures, Deshpande explained. He also believes that this class of drugs is overused and often taken by patients for too long.

There's a need to "be judicious in general, irrespective of this data," Deshpande said. "With PPIs we should really have a targeted endpoint to come off these medications. There is more reason to do that now that we are seeing data that they can have potential side effects."

It is probably also a good idea to shy away from high doses of the heartburn medications, unless absolutely necessary, he said.

"Everything in medicine is a risk/benefit ratio," Deshpande said. "Patients need to talk to their doctor about what they are on the PPI for and look at the risk/benefit ratio and see if they should be on it indefinitely or should be able to come off the PPI."