

Possible Increased Risk of Bone Fractures With Certain Antacid Drugs

There is a possible increased risk of fractures of the hip, wrist, and spine if you take certain drugs for heartburn, acid reflux, or ulcers, warns the Food and Drug Administration (FDA).

The drugs belong to a class of medications called proton pump inhibitors (PPIs), which work by reducing the amount of acid in the stomach. They are available both as prescription and as over-the-counter (OTC) medications.

The prescription PPIs treat conditions such as gastroesophageal reflux disease (GERD), ulcers in the stomach and small intestine, and inflammation of the esophagus. The PPIs available over-the-counter are used to treat frequent heartburn.

The **prescription** PPIs are

- Nexium
- Dexilant
- Prilosec
- Zegerid
- Prevacid
- Protonix
- Aciphex
- Vimovo

The **over-the-counter** PPIs are

- Prilosec OTC
- Zegerid OTC
- Prevacid 24HR

Advice for Consumers

- Do not stop taking your PPI unless you are told to do so by your health care professional. PPIs are effective in treating a variety of gastrointestinal disorders.
- Be aware that an increased risk of fractures of the hip, wrist, and spine have been reported in some studies

of people who use PPIs. The greatest increased risk for these fractures was seen in those who receive high doses of these medications or use them for a year or longer.

- Read and follow the directions on the "Drug Facts" label when considering the use of an over-the-counter PPI.
- Be aware that the over-the-counter PPIs should only be used as directed for 14 days for the treatment of frequent heartburn. If your heartburn continues, talk to your health care professional. No more than three 14-day treatment courses should be used in one year.
- Talk to your health care professional about any concerns you may have about using PPIs.
- Report any side effects from the use of PPIs to FDA's MedWatch Adverse Event Reporting Program either online, by regular mail, by fax, or by phone.
 - Online at www.fda.gov/Safety/MedWatch
 - Regular Mail: Use postage-paid, pre-addressed FDA form 3500 found at www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm
 - Fax: 1-800-FDA-0178
 - Phone: 1-800-332-1088

FDA Actions

FDA has reviewed seven published studies, six of which reported an increased risk of fractures of the hip, wrist, and spine with the use of PPIs. Based on the available data, it is not clear at this time if the use of PPIs is the cause of the increased risk of



fractures seen in some studies. FDA is working with the manufacturers of PPIs to further study this possible risk.

Most of the studies evaluated individuals 50 years of age or older, and the increased risk of fracture was seen mainly in this age group.

As a precaution, FDA is revising the labels for both the prescription and the over-the-counter PPIs to include new safety information about the possible increased risk of fractures of the hip, wrist, and spine with the use of these medications.

Find this and other Consumer Updates at www.fda.gov/ForConsumers/ConsumerUpdates

Sign up for free e-mail subscriptions at www.fda.gov/consumer/consumerenews.html