Proton Pump Inhibitors (PPI): Class Labeling Change

U.S. Food & Drug Administration

Audience: Family Practice, consumers

FDA notified healthcare professionals and patients of revisions to the prescription and over-the-counter [OTC] labels for proton pump inhibitors, which work by reducing the amount of acid in the stomach, to include new safety information about a possible increased risk of fractures of the hip, wrist, and spine with the use of these medications.

The new safety information is based on FDA's review of several epidemiological studies that found those at greatest risk for these fractures received high doses of proton pump inhibitors or used them for one year or more. The majority of the studies evaluated individuals 50 years of age or older and the increased risk of fracture primarily was observed in this age group. While the greatest increased risk for fractures in these studies involved people who had been taking prescription proton pump inhibitors for at least one year or who had been taking high doses of the prescription medications (not available over-the-counter), as a precaution, the "Drug Facts" label on the OTC proton pump inhibitors (indicated for 14 days of continuous use) also is being revised to include information about this risk. FDA recommends healthcare professionals, when prescribing proton pump inhibitors, should consider whether a lower dose or shorter duration of therapy would adequately treat the patient's condition.

The safety communication includes a data summary with a table and references which support the epidemiological studies reviewed for this communication.

[05/25/2010 - Drug Safety Communication [1] - FDA]
[05/25/2010 - Possible Increased Risk of Bone Fractures With Certain Antacid Drugs [2] - FDA Consumer Health Update]

SOURCE [3]

Links:
[1] http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm213206.htm
[2] http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm213240.htm
[3] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanM

edicalProducts/ucm213321.htm