Agency Cautions on PPI-Related Vulnerabilities

BY ALICIA AULT

The Food and Drug Administration issued a warning to physicians and consumers that proton pump inhibitors may increase the risk of hip, wrist, and spine fractures.

The agency said that it is changing the labeling for prescription and over-the-counter versions of proton pump inhibitors (PPIs) to reflect new safety information that is the result of the FDA's review of seven epidemiologic studies. Most of the observed risk was in people older than age 50 years and those who took high doses or used the drugs for more than a year, said the agency.

Prescription PPIs include esomeprazole (Nexium), dexlansoprazole (Dexilant), omeprazole (Prilosec, Zegerid), lansoprazole (Prevacid), pantoprazole (Protonix), and rabeprazole (Aciphex). There are OTC versions of Prilosec, Zegerid, and Prevacid.

"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," Dr. Joyce Korvick, the deputy director for safety in the FDA's Division of Gastroenterology Products, in a statement.

The agency did not have access to the raw data in the studies; it merely reviewed what was published. However, said the FDA, it accepted the results because the studies appear to be well designed.

The full agency communication is online located at www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm213206.htm. ■