

FDA warns of fractures with osteoporosis drugs

October 13 2010, By MATTHEW PERRONE , AP Business Writer

(AP) -- Government health officials warned doctors and patients Wednesday about an increased risk of thigh fractures with a widely used group of bone-strengthening drugs.

The [Food and Drug Administration](#) said patients taking bisphosphonate drugs such as Fosamax and Boniva appear more likely to suffer a rare type of fracture of the femur. The fractures occurred just below the hip joint and make up less than 1 percent of all femur fractures.

"We know from clinical trials that these drugs do prevent the common osteoporosis fractures," said Dr. Sandra Kweder, FDA's deputy director for new drugs. "The fractures we're talking about today are very unusual and rare."

In more than half the cases reported to the FDA, patients experienced pain or aching of the groin before the fracture.

It's unclear whether the drugs directly trigger the problem, but the FDA said it is updating the drugs' labels about the potential risk.

[Bisphosphonates](#) work by slowing the loss of [bone cells](#) that lead to [osteoporosis](#). [Prescription drugs](#) in that class include Merck & Co.'s Fosamax and Roche's Boniva, as well as Procter & Gamble Co.'s Actonel, Warner Chilcott's Atelvia and Novartis' Reclast.

More than 5 million prescriptions for the drugs were written last year,

according to the FDA. The drug is mainly prescribed to women after menopause.

The FDA says patients should continue taking the treatments unless directed to stop by their doctor.

The fractures were publicized in a report last month from the American Society of Bone and Mineral Research, which suggests several explanations for the fractures. One is that the slowdown in cell turnover seen with bisphosphonates could lead to weaker bones in some cases.

The FDA said the fractures "may be related to the use of bisphosphonates for longer than five years." In reviewing reports of [fractures](#), FDA officials said they found patients who had been taking the drugs up to 15 years.

There are no guidelines for how long patients should take the drugs.

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