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FDA warns of thigh fractures with bone drugs

By Lisa Richwine
WASHINGTON | Wed Oct 13, 2010 5:43pm EDT

(Reuters) - Osteoporosis drugs used by millions of women to prevent bones from breaking may increase the chances for an unusual type of thigh fracture, U.S. health officials warned on Wednesday.

The drugs known as bisphosphonates include Merck & Co Inc's Fosamax, Roche Holding AG's Boniva, Novartis AG's Reclast and Warner Chilcott Plc's Actonel.

The action could drive patients to Amgen Inc's just-launched rival medicine, Prolia, a different type of osteoporosis drug that is the company's most important future growth driver.

Food and Drug Administration officials said all bisphosphonates used for osteoporosis will carry a new warning about rare but serious fractures of

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The agency advised doctors to consider if patients on therapy for more than five years still need the drugs.

The new warning "should not cause patients taking bisphosphonates to be fearful of their medicine," said Dr. Sandra Kweder, deputy director of the FDA's new drugs office.

The drugs "are an important mainstay of osteoporosis management" and "have prevented innumerable fractures in their years of use," Kweder told reporters on a conference call.

More than 5 million U.S. patients filled prescriptions for bisphosphonates in 2009, the FDA said.

Concern about thigh fractures may lead patients to seek alternatives such as Amgen's Prolia, Bernstein & Co analyst Geoff Porges said. A positive impact on Prolia could be seen as early as the fourth quarter, he said.

"Today's label change is likely to raise the level of concern among patients about the safety of bisphosphonates significantly," Porges said in a research note.

Osteoporosis is a progressive bone-thinning condition most common in women after menopause. Actonel and Reclast are injectable. The other drugs are taken orally.

The most common fractures seen with osteoporosis typically occur in the hip, wrist or spine. They can cause pain and require hospitalization or surgery.

A study of hospital discharge data showed hip fractures dropped to 428 from 598 per 100,000 people in the 10 years after approval of the first bisphosphonate in 1996, FDA officials said. No treatment eliminates fracture risk completely.

Thigh fractures also can occur from osteoporosis, but the ones reported in recent years were unusual because they often appeared after little or no trauma and were seen in younger patients, the FDA's Kweder said. In most cases, patients felt a dull, aching pain in the thigh or groin months before a complete fracture.

People with those symptoms should contact a doctor to try and prevent the fracture, FDA officials said. The agency is requiring consumer-friendly guides to be dispensed with bisphosphonates to explain possible risks.

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LynnJ wrote:

The package enclosure with most bisphosphonates indicates that one should alert the physician of bone aches. When I told my MD that my forearms were aching constantly, he dc'd the meds, and the ache went away promptly. He suggested that I have a bone scan in another year to see if there was reason to resume the meds. I would suspect the pain in the thigh area is a similar indication that the meds should be - at least temporarily - dc'd.

Oct 14, 2010 4:01pm EDT -- Report as abuse

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