



Fosamax: Is Long Term Use of Bone Strengthening Drug Linked to Fractures?

Popular Class of Osteoporosis Drugs May Have Opposite Effect For Some Women, Experts Say

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Sandy Potter, 59 of Queens, New York, was jumping rope with neighborhood children when she felt her thigh bone snap.

"I went up in the air and I came straight down to the ground," Potter said. "The pain was excruciating."

Potter, who was diagnosed with [osteoporosis](#) at age 48, had been taking [the popular osteoporosis drug Fosamax](#) for eight years before her femur literally snapped in two.

Fosamax, one in a class of drugs called bisphosphonates, is supposed to make bones stronger. But now there's mounting evidence that for some women, taking Fosamax or its generic alendronate for more than five years could cause spontaneous fractures.

"We are seeing people just walking, walking down the steps, patients who are doing low-energy exercise," said Dr. Kenneth Egol, professor of orthopedic surgery at NYU Langone Medical Center. "Very unusual, the femur is one of the strongest bones in the body."

Egol said X-rays of some of his patients look more like an injury endured by a car accident than an otherwise minimal fall.

"Over the last 18 months we are seeing this more frequently," he said.

Sue Heller, 60, of Castle Rock, Colo., had been on Fosamax for almost 10 years. She broke both of her femur bones.

"I'm sure there are a lot of women who have brittle bones right now that maybe are ready to break, and they're not aware of it," said Heller. "And my heart aches for them."

Sales of the popular drug increased when doctors began prescribing it not only to women showing signs of osteoporosis, but also those who were osteopenic, and thus, at risk for the disease. Now some doctors worry that staying on the drug for more than five years can cause some women's bones to become more brittle.

Weighing the Risks

This is not the first time that many doctors have reported an opposite effect for many people taking the drug. Fosamax has already been linked to severe musculoskeletal pain, as well as to a serious bone-related jaw disease called osteonecrosis.

"In worldwide post-marketing experience with FOSAMAX/FOSAMAX Plus D, rare reports consistent with osteonecrosis of the jaw have been received. Many of these reports lack sufficient clinical details to make definitive assessments and/or are confounded, particularly since a generally accepted definition of ONJ in the general population is unknown," responded Merck in a [written response to the suggested link](#). "Rare cases of ONJ have also been reported in patients who do not have osteoporosis and who have not taken any bisphosphonate medicines."

In 2008, the Food and Drug Administration reached out to the pharmaceutical company Merck about the reports of femur fractures. After 16 months, Merck added patients' reports of femur fractures to the list of possible side effects reported by patients included in the drug's package insert.

"It took Merck an entire year to respond," said ABC News senior health and medical editor, Dr. Richard Besser. "Just six words: 'low energy femoral shaft and subtrochanteric fractures.'"

The FDA has also never made an effort to inform the public or doctors across the country who prescribe bisphosphonates of the possible side effect, said Besser.

Both the FDA and Merck declined ABC News' request for an interview. The FDA said they are looking into reports of fractures.

"Nothing is more important to Merck than the safety of its medicines," according to a [written statement by Merck to ABC News](#). A causal relationship between Fosamax and these fractures has not been established, according to Merck.

"The drug companies have to recognize when there is a problem, they have to be up front with the public. If there's a concern, they have to voice it and at least give everybody a fair chance to look at this carefully," said Dr. Joseph Lane, orthopedic trauma surgeon at the Hospital for Special Surgery in New York City.

How Much for How Long

Many studies suggest an overall benefit from taking the medication for women who are at risk for osteoporosis. In fact, bisphosphonates can help prevent hip and spine fractures, which for many women may lead to death.

"Normally your bone is constantly being remade," said Dr. Joseph Lane, chief of metabolic bone disease at the Hospital for Special Surgery in New York City. "These patients don't remake their bone and they acquire damage, microdamage, the collagen gets altered and we need to rejuvenate the skeleton."

In 2008, bisphosphonate sales exceeded \$3.5 billion according to data from IMS Health. In 2008, over 37 million prescriptions were written for the osteoporosis medications.

While some physicians use bone density scans to help drive their decisions, doctors generally prescribe them to women who are at an increased risk for either osteoporosis or fractures from osteoporosis they already have. A [new tool developed by the World Health Organization](#) can determine the risk of having fractures and can help doctors determine which women with osteoporosis should be treated with medications.

Although bisphosphonates are generally recommended for postmenopausal women, research does not indicate how long women should be on the drug. Many doctors now recommend a five-year limit.

"When they are on it for five, six, seven or eight years, they lost their ability to remodel and regenerate their skeleton," said Lane. "[Some women] are very vulnerable and they will then develop problems of brittle bone."

Additional time on the medication depends on doctors' orders, said Besser.

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