



## **Drug for Bone Disease Linked to 'Jaw Death'**

**Researchers Report Cases of Osteonecrosis of Jaw in Patients Who Had Teeth Pulled**

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WebMD Medical News

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on Monday, October 03, 2005

Oct. 3, 2005 -- Millions of people treated for bone diseases such as osteoporosis may be at risk for developing a potentially serious jawbone condition that seems to be triggered by having teeth pulled. More than a thousand cases of osteonecrosis of the jaw, or jaw death, have been reported in patients taking a class of drugs known as bisphosphonates. Osteonecrosis indicates that part of the bone is no longer alive; unlike normal bone it cannot regenerate itself because of a lack of blood supply.

Most cases occurred in cancer patients taking the intravenous bisphosphonates Aredia and Zometa to prevent cancer-related bone loss. But osteonecrosis of the jaw has also been reported in women who had teeth pulled while taking the widely prescribed osteoporosis pill Fosamax, dentistry professor Ken Hargreaves, DDS, PhD, tells WebMD.

"Even if this is a rare condition, so many women now take bisphosphonates to prevent bone loss that the numbers could grow," he says. "We just became aware of this a few years ago, and it has been called a growing epidemic."

The study appeared in the October issue of the *Journal of Endodontics*.

### **Saving Teeth Lowers Risk**

A newly published report edited by Hargreaves outlines two cases of osteonecrosis of the jaw in cancer patients on monthly doses of intravenous bisphosphonates.

He says it is clear from these and other published cases that patients taking bisphosphonates should be warned that they may be at risk if they have teeth pulled. Osteonecrosis of the jaw is very painful and can lead to serious complications, including ulcerations within the lining of the mouth, infection, and breakdown of the jawbone with disfigurement.

"People taking these drugs need to see their dentist regularly, and they need to recognize the importance of preventive dental care," he says. "And when there is a problem, we need to do everything we can to save teeth."

That means performing root canals on patients taking these drugs rather than tooth extractions, he says.

### **Dental Extraction and Jaw Death**

Drug maker Novartis AG, which markets Aredia and Zometa, also recommends that cancer patients have dental problems corrected before they begin taking either of the drugs. Novartis is a WebMD sponsor.

Yet the researchers also write that a significant number of cases of reported osteonecrosis of the jaw have occurred spontaneously.

In response to an inquiry by WebMD, a company spokeswoman said approximately 1,500 cases of osteonecrosis of the jaw had been reported among patients taking the drugs as of August of this year. More than 2.8 million cancer patients have been treated with Aredia or Zometa to reduce the risk of cancer-related bone fractures.

In a review of 4,000 patients taking either Aredia or Zometa, 33 patients, or less than 1%, developed the jaw disease.

The study confirmed that having teeth removed put patients at risk for the condition. It was funded by Novartis and conducted by researchers at Houston's University of Texas M.D. Anderson Cancer Center. The findings were reported late last month at the annual meeting of the American Society of Bone and Mineral Research.

"Based on previous findings and the recent M.D. Anderson Cancer Center report, Novartis strongly believes that improving dental care needs to be a priority for cancer patients," states a company news release.

### **Oral Bisphosphonates and Osteonecrosis**

The risks associated with taking bisphosphonates in pill form, like Fosamax, are not well understood. In a study of 63 patients who developed the jaw condition following oral surgery, about 10% had been taking Fosamax to prevent osteoporosis.

Researchers concluded that bisphosphonates in pill form do not appear to be as likely to cause jaw death as the intravenous versions of the drug. Considering the large number of patients around the world using bisphosphonates for prevention or treatment of osteoporosis, dentists may be dealing with a significant potential complication, they add.

But the FDA has called on the manufacturers of all bisphosphonates to include a warning on their labeling about the risk of osteonecrosis of the jaw, which Fosamax manufacturer Merck did earlier this year. Merck is a WebMD sponsor.

In its label change, the drugmaker noted that it is not clear if patients taking bisphosphonates can lower their risk by stopping treatment prior to having teeth pulled or other dental procedures.

But these medications are metabolized slowly and remain in the bone for many years. It is widely believed that stopping treatment does little good. And once jaw death occurs there is little that can be done to reverse the condition, Hargreaves says.

"The best thing we can do is prevent this from occurring by helping patients reduce their risk," Hargreaves says. "That means saving teeth instead of pulling them."