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FDA Statement on ASBMR report: Possible Increased Risk of Certain Types of Thigh Bone Fractures with Long-Term Bisphosphonates Use

[9/14/2010] FDA appreciates the report from the American Society of Bone and Mineral Research's (ASBMR's) expert Task Force, released today, providing important perspectives on the potential association between long term treatment with the class of osteoporosis drugs known as bisphosphonates and a rare but serious type of fracture of the thigh bone (femur). The report includes a case definition that describes the atypical features of these unusual femur fractures. FDA believes this case definition will help greatly in identifying cases and reporting on them, and should facilitate future studies comparing the frequency of these unusual fractures both in patients treated with bisphosphonates and those who have not received bisphosphonates.

Bisphosphonates have long been effective in reducing common bone fractures in individuals with osteoporosis. Although it is not clear if bisphosphonates are the cause, these unusual femur fractures have been identified in patients taking these drugs. FDA recommends that healthcare professionals be aware of the possible risk of unusual femur fractures in patients taking bisphosphonates. Patients should talk to their healthcare professional if they develop new thigh or groin pain so that they may be evaluated to rule out a femur fracture. Patients should not stop taking their medication unless told to do so by their healthcare professional. Patients and healthcare professionals should report any side effects with the use of bisphosphonates to FDA's MedWatch program.

The optimal duration of bisphosphonate treatment for osteoporosis is unknown. Clinical trial data for bisphosphonates approved for the prevention and/or treatment of osteoporosis support effectiveness for the reduction of common bone fractures for three to five years.

Since the initial report of unusual fractures with bisphosphonates was published, FDA has been diligently monitoring this issue. We have been reviewing all the scientific data available regarding their safety and effectiveness when used for more than three to five years for the treatment and prevention of osteoporosis. We have talked with patient groups and have requested clinical trial data from the manufacturers of bisphosphonate products as part of this ongoing safety review.

The ASBMR Task Force's recommendations include recommended changes to product labels alerting healthcare professionals and patients to the possibility of unusual femur fractures with long-term use of bisphosphonates. FDA has assembled and is thoroughly reviewing all long term data available on the products, as well as all safety reports, and is considering label revisions. FDA will keep the public informed of additional findings and actions on this issue.

Related Information

- [Bisphosphonates \(marketed as Actonel, Actonel+Ca, Aredia, Boniva, Didronel, Fosamax, Fosamax+D, Reclast, Skelid, and Zometa\) Information¹](#)

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WO51-2201

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