Possible Fracture Risk With Osteoporosis Drugs

The Food and Drug Administration (FDA) is warning there is a possible risk of a rare type of thigh bone (femoral) fracture in people who take drugs known as bisphosphonates to treat osteoporosis.

The agency warned patients and health care professionals of this risk on Oct. 13, 2010, because the rare type of femoral fracture has been predominantly reported in patients taking these prescription medications.

FDA says the possible risk of thigh fracture will be reflected in a labeling change for bisphosphonate medications that treat osteoporosis and in a medication guide that will be required to be given to patients when they pick up their prescription.

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FDA says it is not clear whether bisphosphonates are the cause of the unusual bone breaks known as subtrochanteric femur fractures, which occur just below the hip joint, and diaphyseal femur fractures, which occur in the long part of the thigh.

Medication Guide, Labeling Change

The changes to labeling and the medication guide will affect only bisphosphonates approved for osteoporosis. These include

- oral bisphosphonates such as Actonel, Actonel with Calcium, Atelvia, Boniva, Fosamax, Fosamax Plus D, and their generic products
- injectable bisphosphonates such as Boniva and Reclast and their generic products

Labeling and the medication guides for bisphosphonates that are used for other conditions will not change.

FDA says the optimal duration of bisphosphonates treatment for osteoporosis is unknown—an uncertainty the agency is highlighting because these fractures may be related to use of bisphosphonates for longer than five years.

FDA medical officer Theresa Kehoe, M.D., says the agency continues to evaluate data about the safety and effectiveness of bisphosphonates when used long-term for osteoporosis treatment.

"In the interim, it's important for patients and health care professionals to have all the safety information available when determining the best course of treatment for osteoporosis," she says.

Advice for Consumers

If you are currently taking bisphosphonates for osteoporosis, FDA advises that you

- keep taking your medication unless you are told to stop by your health care professional
- read the medication guide. It will describe the symptoms of an atypical femur fracture. The guide also advises you to notify your health care professional if you develop symptoms
- tell your health care professional if you develop new hip or thigh pain (commonly described as dull or aching pain), or have any concerns with your medications
- report any side effects with your bisphosphonate medication to FDA's MedWatch program
  - online: *www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm*
  - by regular mail: Use postage-paid, pre-addressed FDA form 35004, available online at *www.accessdata.fda.gov/scripts/medwatch/*
  - by Fax: (800) FDA-0178
  - by phone: (800) FDA-1088

FDA also recommends that health care professionals be aware of the possible risk in patients taking bisphosphonates and consider periodic reevaluation of the need for continued bisphosphonate therapy, particularly for patients who have been on bisphosphonates for longer than five years.

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