How Long Should You Take Osteoporosis Drugs?

Researchers at the Food and Drug Administration (FDA) have taken a close look at the long-term benefit of bisphosphonates, a class of medications widely prescribed to treat osteoporosis.

An FDA review of clinical studies measuring the effectiveness of long-term bisphosphonates use shows that some patients may be able to stop using bisphosphonates after three to five years and still continue to benefit from their use, says Marcea Whitaker, M.D., a medical officer at FDA's Cen-

Reduce Your Risk

A number of factors put both men and women at risk for osteoporosis, including age, race, family history, and a sedentary lifestyle. But there are also several ways you can reduce that risk, including:

- getting adequate amounts of calcium and Vitamin D through foods
- staying physically active, including weight-bearing exercise such as walking, jogging, skipping rope, and skiing
- not smoking
- limiting alcohol use

If you do make the decision to discontinue use, talk to your physician before stopping therapy.

ter for Drug Evaluation and Research. Whitaker is one of the co-authors of the FDA review, which was published in the May 31, 2012 issue of The New England Journal of Medicine.

If you're one of the 44 million Americans at risk for osteoporosis—a disease in which bones become weak and are more likely to break—you may be taking bisphosphonates. This class of drugs has been successfully used since 1995 to slow or inhibit the loss of bone mass. Doctors commonly prescribe such brand-name drugs as Actonel, Atelvia, Boniva, and Fosamax (as well as a number of generic products) for osteoporosis. In fact, more than 150 million prescriptions were dispensed to patients between 2005 and 2009.

According to the review, further investigation is needed on the long-term risks and benefits of these drugs.

"These drugs clearly work," Whitaker says. "We just don't know yet the optimum period of time individual patients should be on the drug to both maximize its effectiveness and minimize potential risks." More research is needed on patients' risk of fracture after they stop taking bisphosphonates, and whether taking them again later on could prove beneficial, she adds. As always, patients should talk to their health care provider about their continued need for therapy.

The studies suggest that patients at low risk of fracture (for example, younger patients without a fracture history and with a bone mineral density approaching normal) may be good candidates for discontinuation of bisphosphonate therapy after three to five years.

In contrast, patients at increased risk for fractures (for example, older patients with a history of fracture and a bone mineral density remaining in the osteoporotic range) may benefit further from continued bisphosphonate therapy.

How the Medication Works

Bones go through a continual process of remodeling, in the form of bone resorption (disintegration) and bone formation. Bone loss related to osteoporosis occurs when resorption is greater than formation. Bisphosphonates decrease bone resorption, thereby slowing bone loss.

During treatment, bisphosphonates become part of the newly formed bone and can stay there for years, through many cycles of resorption and formation. Patients continue to be exposed to the effects of the drug even long after they've stopped taking it.

According to Whitaker, the studies that FDA considered focused on patients who had been using bisphosphonates for at least three years and as many as 10. They looked at outcomes related both to bone mineral density and bone fractures.

"Bisphosphonates have been proven very effective in protecting against bone fractures in clinical trials lasting three to four years," says Whitaker. But it's still unknown whether the benefit lasts longer than that in decreasing the risk of fractures.

Bisphosphonate labels have carried a safety warning about severe jaw bone decay (osteonecrosis of the jaw) since 2002. In October 2010, FDA warned patients and health care professionals about the increased risk of unusual thigh bone fractures and directed manufacturers to include the warning in the safety labels and medication guides that come with prescription medications. FDA continues to evaluate a possible association of bisphosphonates with esophageal cancer. These associations would suggest that health care professionals may want to reconsider how long patients should continue taking the drugs.

What Should a Patient Do?

Decisions to continue treatment must be based on individual assessments of risks and benefits and on patient preference, Whitaker says

If you are taking bisphosphonates:

- Talk to your physician about whether or not you should continue this therapy. Re-evaluate the decision on a periodic basis.
- Don't stop taking these (or any) prescribed drugs without talking to your physician first. If you do make the decision to discontinue use, talk to your physician before stopping therapy.
- 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 unusual side effects of your bisphosphonate medication to FDA's MedWatch program.

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