

Osteoporosis Medications

Several medications are approved by the Food and Drug Administration (FDA) for the prevention and treatment of osteoporosis. Since all medications have side effects, it is important to talk to your doctor about which medication is right for you. The following is excerpted from the National Institute of Arthritis and Musculoskeletal and Skin Diseases¹ and the National Osteoporosis Foundation,² unless otherwise noted.

Bisphosphonates

Alendronate, risedronate, ibandronate, and zoledronic acid are from a class of drugs called bisphosphonates that slow bone loss, reduce fracture risk, and in some cases increase bone density. These drugs decrease the activity of bone-dissolving cells.¹

Alendronate is an oral medication in pill or liquid form and is available in daily and weekly doses for treating women and men. Risedronate is available in pill form in daily, weekly, and twice-monthly doses for treating women and men. Ibandronate is available in a pill as a monthly dose or as an intravenous injection given once every three months for treating women. Zoledronic acid is available as an intravenous injection, given once a year for treating women. Side effects of taking oral bisphosphonates may include nausea, heartburn, and stomach pain, including serious digestive problems if they are not taken properly.¹

A few people have muscle, bone, or joint pain while using these medicines. Side effects of intravenous bisphosphonates may include flu-like symptoms such as fever, pain in muscles or joints, and headaches. These symptoms usually stop after a few days. In rare cases, osteonecrosis of the jaw [bone collapse due to loss of their blood supply³] has occurred in people taking bisphosphonates.¹

“Patients and healthcare professionals may have questions about oral bisphosphonate medications and atypical subtrochanteric femur fractures – fractures in the bone just below the hip joint....Recent news reports have raised the question about whether there is an increased risk of this type of fracture in patients



with osteoporosis using these medications. At this point, the data that FDA has reviewed have not shown a clear connection between bisphosphonate use and a risk of atypical subtrochanteric femur fractures....Based on published case reports of atypical subtrochanteric femur fractures occurring in women with osteoporosis using bisphosphonates, FDA, in June 2008, requested information from all bisphosphonate drug manufacturers regarding this potential safety signal. All available case reports and clinical trial data were requested. FDA’s review of these data did not show an increase in this risk in women using these medications.

In addition, FDA reviewed a December 2008 article in the *Journal of Bone and Mineral Research* by Abrahamsen et al.¹ that analyzed data from two large observational studies in patients with osteoporosis. The authors concluded that atypical subtrochanteric femur fractures had many similar features in common with classical osteoporotic hip fractures, including patient age, gender, and trauma mechanism. The data showed that patients taking bisphosphonates and those not taking bisphosphonates had similar numbers of atypical subtrochanteric femur fractures relative to classical osteoporotic hip fractures.”⁴

“FDA recommends that healthcare professionals follow the recommendations in the drug label when prescribing oral bisphosphonates. [FDA recently approved updated labeling of bisphosphonates,

which denotes the [possible risk of atypical thigh bone fractures](#).]

Patients should continue taking oral bisphosphonates unless told by their healthcare professional to stop. Patients should talk to their healthcare professional if they develop new hip or thigh pain or have any concerns with their medications.”⁵

Estrogen

Estrogen is approved for the treatment of menopausal symptoms and osteoporosis. Because of recent evidence that breast cancer, strokes, blood clots, and heart attacks may be increased in some women who take estrogen, the FDA recommends that women take the lowest effective dose for the shortest period possible. Estrogen should only be considered for women at significant risk for osteoporosis, and nonestrogen medications should be carefully considered first.¹

Selective Estrogen Receptor Modulators (also called estrogen agonists/antagonists)

Raloxifene, available as a daily pill, is approved for use in postmenopausal women. From a class of drugs called estrogen agonists/antagonists, commonly referred to as selective estrogen receptor modulators (SERMs), raloxifene is a nonhormonal drug that has estrogen-like effects on the skeleton but blocks estrogen’s effects in the breast and uterus. Raloxifene slows bone loss and reduces the risk of fractures in the spine, but no effect on hip fracture has been seen. Side effects may include hot flashes and an increased risk of blood clots in some women.¹

Calcitonin

Calcitonin, available as a daily nasal spray or injection, is approved for the treatment of osteoporosis in women who are at least 5 years past menopause. It is a hormone produced by the thyroid gland that slows bone loss and reduces the risk of spine fractures.¹ The main side effects are nasal irritation from the spray form and nausea from the injectable form.⁶ In rare cases, severe allergic reaction (bronchospasm, swelling of the tongue or throat, anaphylactic shock) has been reported with calcitonin injection.⁷

Parathyroid Hormone

Teriparatide, a form of human parathyroid hormone, stimulates new bone formation. Given as a daily injection for up to 24 months, it increases bone tissue

and bone strength, and it has been shown to reduce the risk of spine and other fractures. Teriparatide is approved for use in postmenopausal women and men who are at *high risk* of fracture. Some patients experience leg cramps and dizziness from teriparatide.¹

RANK Ligand (RANKL) Inhibitor

In June 2010, Denosumab was approved by the FDA for the treatment of osteoporosis in postmenopausal women at high risk of fracture or breaking a bone. According to the package insert, being at high risk of fracture means that you meet one or more of the following conditions:

- you have already broken a bone from osteoporosis,
- you have several risk factors for breaking a bone,
- you have not been able to take other osteoporosis medicines due to side effects, or
- you have not received enough benefit from other osteoporosis medicines.²

Denosumab is a RANK ligand (RANKL) inhibitor/human monoclonal antibody. A healthcare professional gives denosumab by injection every six months. Patients need to have a blood test before each dose to confirm that their blood calcium level is normal. In clinical trials, denosumab significantly reduced the incidence of new spine fractures by 68 percent, reduced the incidence of hip fractures by 40 percent, and reduced the incidence of all non-spine fractures by 20 percent over three years.²

Denosumab, however, may lower the calcium levels in the blood. If blood calcium levels are low before receiving denosumab, the low calcium level must be corrected before giving the medicine or it will get worse. Signs of low calcium levels include spasms, twitches or cramps in the muscles; or numbness and tingling in the fingers, toes, or around the mouth. If any of these symptoms are seen while on this medicine, patients should contact their healthcare provider. Most patients with low calcium levels, however, do not show these signs.²

People who have weak immune systems or take other medicines that affect the immune system may have an increased chance of having serious infections with denosumab. Even patients who have no immune system problems may be at higher risk of certain infections, such as those of the skin. Patients should contact their healthcare provider right away if signs of infection occur. These signs may include fever, chills, red and swollen skin, skin that is hot or sore

to the touch, severe pains in the abdomen, or pain or burning when passing urine or passing urine more frequently and in small amounts.²

Denosumab may also cause skin rashes. Call your healthcare provider if you notice any abnormal skin-related symptoms. Denosumab has caused osteonecrosis of the jaw (ONJ) when used to treat patients with cancer, although at this time, these have not been seen in patients with osteoporosis. Patients should practice good dental care during treatment and should have an examination of the mouth by a doctor or dentist before starting the medicine.²

Side effects can also include back pain and musculoskeletal pain in the arms and legs.²

Sources

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