



PATIENT RESOURCES

Osteoporosis Treatment

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Osteoporosis, which means porous bones, is a progressive condition in which bones become structurally weak and are more likely to fracture or break. Even with a healthy lifestyle, you may need additional therapy to protect against bone loss and fractures. Your doctor may need to prescribe medications such as:

- > Bisphosphonates (alendronate, risedronate, ibandronate, zoledronic acid)
- > Raloxifene

- › Teriparatide
- › Abaloparatide
- › Romosozumab
- › **Estrogen** (when also prescribed for the relief of menopausal symptoms)
- › Calcitonin

These treatment options are effective but may have side effects. Talk with your doctor to determine whether you need treatment and which option is best for you. The U.S. Food and Drug Administration (FDA) has approved several medications for preventing and treating osteoporosis.

› **Bisphosphonates**

Bisphosphonates are the kind of medicine used most often to treat osteoporosis. They do this by:

- › Preventing bones from getting weaker by slowing the natural breakdown of bone.
- › Lowering the risk of spine fractures and most lower the risk of hip fracture and other kinds of fractures as well.
- › Preventing and treating postmenopausal osteoporosis by slowing bone loss while increasing bone density mass.

Several types of bisphosphonates are available, in pill or liquid form. Some are given intravenously (IV), which means the medicine is injected into a vein at the doctor's office or a hospital. Bisphosphonate medications include:

- › Alendronate (Fosamax®). Tablet available in daily and weekly forms
- › Risedronate (Actonel, Atelvia®). Tablet available in daily, weekly, and monthly forms
- › Ibandronate (Boniva®). Available in monthly tablet or as an injection once every three months
- › Zoledronic Acid (Reclast®). An intravenous infusion given once a year for treatment, or every two years for prevention

The bisphosphonates alendronate, risedronate, and zoledronic acid have also been approved for the treatment of steroid-induced osteoporosis in men and women who need long-term use of medications to treat inflammatory conditions (which can contribute to osteoporosis).

Side effects of bisphosphonates are uncommon, but may include abdominal, bone, or muscle pain. These medications may also cause nausea or heartburn. Tablet forms may cause irritation of the esophagus.

Experts say that the benefits of taking bisphosphonates greatly outweigh the risks for most people with osteoporosis. Overall, when you take this type of medicine, your chance of preventing fractures is high, and the risk of serious problems is low.

However, side effects of bisphosphonates can include:

- › Nausea, heartburn, swallowing problems, or irritation of the esophagus (the tube that carries food and liquid from your mouth to your stomach)
- › Pain in the muscles, joints, bones, or stomach

Some people have reported serious side effects, but studies have shown that these are very rare. Bisphosphonates has been linked to osteonecrosis

(degeneration) of the jaw bone, particular after high-dose, long-term therapy, as might be given during cancer treatment. The risk of osteonecrosis of the jaw is greatest after dental operations. There is also a concern that long-term treatment may increase the risk of so-called atypical femoral fractures—fractures through the shaft of the thigh bone with little or no trauma.

Bisphosphonates are not recommended for premenopausal women who may become pregnant or for people with severely impaired kidney function.

If you take a bisphosphonate and you're having side effects, tell your doctor. Your doctor might give you a different kind of medicine to overcome the side effects. For example, taking medicine through an IV instead of swallowing a pill can overcome heartburn.

► **Denosumab**

Denosumab is also approved as first-line therapy to treat bone loss, but it is commonly used when patients cannot tolerate other osteoporosis medicines or if other medicines are not working well. The medication is also used for preventing and treating osteoporosis in postmenopausal women who are at increased risk for fractures.

Denosumab can be used to treat bone loss in women who are receiving treatment for breast cancer. It is also used to prevent bone problems in patients with bone metastases (cancer that has spread to the bones) from

certain types of tumors.

Denosumab is injected under the skin, usually by a doctor or nurse. When denosumab is used to treat osteoporosis, it is usually injected once every 6 months. When is used to reduce fractures from cancer that has spread to the bones, it is usually injected once every 4 weeks. Denosumab can also be used in people with reduced kidney function as the medication is not cleared from the body by the kidneys.

Denosumab may cause sides effects. Call your doctor right away if you have a serious side effect such as:

- › Numbness or tingling around your mouth or in your fingers or toes
- › Fast or slow heart rate
- › Muscle cramps or contraction
- › Overactive reflexes
- › Trouble breathing

Less serious side effects of denosumab may include:

- › Feeling weak or tired
- › Diarrhea, nausea
- › Headache

Denosumab has also been linked to osteonecrosis of the jaw and atypical femoral fractures—and to multiple spinal fractures if treatment is discontinued. It's important for both safety and the effectiveness of therapy to stick as closely as possible to the injection schedule. This is not a complete list of side effects and others may occur. Ask your doctor for medical advice about side effects.

► Raloxifene

Raloxifene is approved for preventing and treating osteoporosis in postmenopausal women. It is from a class of drugs called selective estrogen receptor modulators (SERMs), which are estrogen-like medications. SERMs act like estrogen in some parts of the body but block the effects of estrogen in other parts.

Raloxifene increases bone density and reduces the risk of spine fractures, but it has not been shown to decrease the risk of non-spinal fractures. Raloxifene also decreases the risk of invasive breast cancer.

Raloxifene is taken in pill form, once a day, with or without meals. While uncommon, side effects may include hot flashes, leg cramps, or blood clots in the legs or lungs. Raloxifene is not recommended for premenopausal women.

► Teriparatide

Teriparatide is a part of the parathyroid hormone molecule, which is a naturally occurring hormone that regulates calcium levels in the body. Teriparatide treatment stimulates new bone formation, rather than preventing bone breakdown. Because of potential safety concerns, particularly an increased risk of bone cancer in rats, the use of this drug is restricted to men and women with severe osteoporosis—who have a high risk of a fracture—and can be given for no more than two years. Teriparatide treatment is followed by switching to a different kind of medication to

maintain the gain in bone density and strength.

Teriparatide is given as a daily, self-administered injection. Side effects are uncommon but may include leg cramps, headaches, dizziness, high blood calcium and high urinary calcium (with an increased risk of kidney stones). This medication is not recommended for premenopausal women.

► **Abaloparatide**

Abaloparatide is also a bone-building medication that is given as a daily, self-administered injection under the skin for no more than two years. It has been shown to reduce the risk of both spine and non-spine fractures. It, too, is followed by another medication designed to maintain bone gain.

Abaloparatide is approved for the treatment of women after menopause at high risk of fracture, defined as those women with a history of osteoporotic fracture, multiple risk factors for fracture, or women who have failed or have side effects with other available osteoporosis therapies. Abaloparatide also has a safety warning about an increased risk of bone cancer in rats, and may cause dizziness, nausea, high blood calcium or high urinary calcium (with an increased risk of kidney stones).

► **Romsozumab**

Romsozumab is a bone-building medication that is given once a month as pair of injections by a doctor or nurse. Treatment is given once a month for twelve months and is then followed by another medication to prevent bone loss. Romsozumab reduces the risk of spine fractures and non-spine

fractures, including hip fractures. Romosozumab may increase the risk of heart attack or stroke—including fatal heart attack or stroke—and it should not be given to women who have had a heart attack or stroke in the past year. It is approved for the treatment of osteoporosis in women past the time of menopause who are at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture, or failure or intolerance to other available osteoporosis therapies. It may cause side effects such as headache or joint pain.

► **Estrogen**

Estrogen hormone therapy prevents bone loss and reduces the risk of fracture in the spine and hip. It can also relieve other symptoms of menopause, such as hot flashes and vaginal dryness. Estrogen is usually given in pill form, although it is also available in other forms such as a skin patch or gel.

Studies show that the risks of estrogen therapy—including heart attack, stroke, blood clots, and breast cancer—may outweigh its benefits in many older women, depending upon the dose and specific preparation. For this reason, estrogen therapy is not usually prescribed solely for fracture prevention. In fact, even when estrogen is used to treat menopausal symptoms, the U.S. Food and Drug Administration recommends that it be used in as low a dose, for as short a time, as needed.

► **Treatment and Therapies For Men**

Alendronate, risedronate, zoledronic acid, teriparatide, and denosumab have been approved to treat osteoporosis in men. Denosumab is also approved to protect bone mass in men taking androgen deprivation therapy for prostate cancer. Although there are fewer studies in men, the effects of these medications on bone mass are similar to their effects in women and are likely helpful in treating men with osteoporosis.

The question of whether testosterone supplementation is useful for treatment of osteoporosis in men remains controversial. In men who clearly have low levels of testosterone, treatment with testosterone appears to increase bone density. However, the doses necessary and the best way to administer this treatment are unclear. There is no information about whether testosterone treatment in men is effective in reducing fracture risk.

Finally, the risks of long-term testosterone treatment in older men are unknown. At present, it is generally not recommended that testosterone be used as the primary osteoporosis treatment for men. Other approved osteoporosis treatments for men are effective in men with low testosterone levels.

► **Questions to Ask Your Healthcare Provider**

- › Am I at risk for osteoporosis?
- › Do I need a bone density test?
- › How often should I have a bone density test?
- › Should I take calcium and vitamin D supplements? How much do I need?
- › Should I be taking medicine to protect my bones?
- › What else can I do to keep my bones strong?

- › Should I see an endocrinologist?
- › Do any of my medicines cause bone loss?
- › Are there different medicines I can take?
- › What should I do to protect my bones?

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