

For men at high risk for fracture receiving certain treatments for prostate cancer

Bone Loss: Information You Can Use

How can my prostate cancer treatment lead to bone loss?

A possible side effect of your treatment with hormone therapy, or androgen deprivation therapy (ADT), is bone loss. This bone loss can put you at high risk for fractures.¹

How can I help protect against this type of bone loss?

You may have already been prescribed calcium and vitamin D supplements. In addition to calcium and vitamin D, your doctor has prescribed Prolia® for you.¹

What is Prolia®?

Prolia® is the only prescription medicine that is FDA-approved to treat bone loss in men who are at high risk for fracture receiving certain treatments for prostate cancer that has not spread to other parts of the body.²

Prolia® can help strengthen your bones by helping to increase bone density and lower your risk of fracture. Prolia® is given as a single shot by a health care professional under the skin (subcutaneous) once every 6 months.²

Important Safety Information

Do not take Prolia® if you have low blood calcium; or are pregnant or plan to become pregnant, as Prolia® may harm your unborn baby; or are allergic to denosumab or any ingredients in Prolia®. Prolia® can cause serious side effects. Possible serious side effects include serious allergic reactions, low calcium levels in your blood, severe jaw bone problems, unusual thigh bone fractures, serious infections, and skin problems.

Please turn to the reverse side for additional Important Safety Information about Prolia®.

What additional resources are available for support?

Visit this website for more information and support for you and your caregivers*:

Us Too International Prostate Cancer Education and Support Network
www.ustoo.org

*This third party resource is for the reader's information only. Unless otherwise specified, Amgen does not endorse and is not responsible for the content included in this resource.

References: 1. Smith MR, Egerdie B, Hernandez Toriz N, et al, for the Denosumab HALT Prostate Cancer Study Group. Denosumab in Men Receiving Androgen-Deprivation Therapy for Prostate Cancer. *N Engl J Med*. 2009;361:745-55. 2. Prolia® [denosumab] prescribing information, Amgen.



Important Safety Information

Do not take Prolia® if you have low blood calcium; or are pregnant or plan to become pregnant, as Prolia® may harm your unborn baby; or are allergic to denosumab or any ingredients in Prolia®.

What is the most important information I should know about Prolia®?

If you receive Prolia®, you should not receive XGEVA®. Prolia® contains the same medicine as XGEVA® (denosumab).

Prolia® can cause serious side effects:

Serious allergic reactions have happened in people who take Prolia®. Call your doctor or go to your nearest emergency room right away if you have any symptoms of a serious allergic reaction, including low blood pressure (hypotension); trouble breathing; throat tightness; swelling of your face, lips, or tongue; rash, itching, or hives.

Low blood calcium (hypocalcemia). Prolia® may lower the calcium levels in your blood. If you have low blood calcium, it may get worse during treatment. Your low blood calcium must be treated before you receive Prolia®. Take calcium and vitamin D as your doctor tells you to help prevent low blood calcium.

Severe jaw bone problems (osteonecrosis) may occur. Your doctor should examine your mouth before you start Prolia® and may tell you to see your dentist. It is important for you to practice good mouth care during treatment with Prolia®.

Unusual thigh bone fractures. Some people have developed unusual fractures in their thigh bone. Symptoms of fracture include new or unusual pain in your hip, groin, or thigh.

Serious infections in your skin, lower stomach area (abdomen), bladder, or ear may happen. Inflammation of the inner lining of the heart (endocarditis) due to an infection may also happen more often in people who take Prolia®. You may need to go to the hospital for treatment.

Prolia® is a medicine that may affect the ability of your body to fight infections. People who have weakened immune systems or take medicines that affect the immune system may have an increased risk for developing serious infections.

Skin problems such as inflammation of your skin (dermatitis), rash, and eczema have been reported.

Bone, joint, or muscle pain. Some people who take Prolia® develop severe bone, joint, or muscle pain.

Before taking Prolia®, tell your doctor if you:

- Take the medicine XGEVA® (denosumab). XGEVA® contains the same medicine as Prolia®.
- Have low blood calcium
- Cannot take daily calcium and vitamin D
- Had parathyroid or thyroid surgery (glands located in your neck)
- Have been told you have trouble absorbing minerals in your stomach or intestines (malabsorption syndrome)
- Have kidney problems or are on kidney dialysis
- Plan to have dental surgery or teeth removed
- Are pregnant or plan to become pregnant.
 - **If you are a man and you receive Prolia®,** small amounts of Prolia® may be in semen. If your sexual partner is pregnant, some Prolia® from your semen may reach the unborn baby. While the risk is likely to be low, it is important to talk to your doctor if your partner becomes pregnant while you are taking Prolia®.

What are the possible side effects of Prolia®?

It is not known if the use of Prolia® over a long period of time may cause slow healing of broken bones. The most common side effects of Prolia® in patients receiving certain treatments for prostate or breast cancer are joint pain, back pain, pain in your arms and legs, and muscle pain. Also, men treated with Prolia® receiving certain treatments for prostate cancer had a greater rate of cataracts.

These are not all the possible side effects of Prolia®. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see accompanying full Prescribing Information, including Medication Guide.

Amgen offers financial assistance for Prolia®, regardless of your existing coverage. For more information, please contact:

Amgen Assist®

Phone: 1-888-4-ASSIST (1-888-427-7478)

www.AmgenAssistOnline.com

Talk to your doctor if you have any other questions about Prolia®.

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Oncology

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prolia®
(denosumab) injection