

# Questions To Ask Your Doctor



- What more can I do to strengthen and protect my bones?
- What was the result of my last bone density scan?
- What does the result of my bone density scan or T-score mean?
- Are my bones getting stronger with my current therapy?
- After I take my medication, my throat often burns, or I get a sour taste in my mouth. Is there another option?
- Could Prolia® be right for me?

**Are you ready to help strengthen your bones?  
Talk with your doctor to see if Prolia® is right for you.**

## Indications

Prolia® is a prescription medicine used to treat osteoporosis in women after menopause who are at high risk for fracture or cannot use another osteoporosis medicine or other osteoporosis medicines did not work well.

Prolia® is a prescription medicine used to increase bone mass in men with osteoporosis who are at high risk for fracture.

## 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 a fracture include new or unusual pain in your hip, groin, or thigh.

**Increased risk of broken bones, including broken bones in the spine, after stopping, skipping or delaying Prolia®.** Talk with your doctor before starting Prolia® treatment. After your treatment with Prolia® is stopped, or if you skip or delay taking a dose, your risk for breaking bones, including bones in your spine, is increased. Your risk for having more than 1 broken bone in your spine is increased if you have already had a broken bone in your spine. Do not stop, skip or delay taking Prolia® without first talking with your doctor. If your Prolia® treatment is stopped, talk to your doctor about other medicine that you can take.

**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 about all of your medical conditions, including if you:**

- Take the medicine XGEVA® (denosumab)
- 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
- Are taking medicine that can lower your blood calcium levels
- Plan to have dental surgery or teeth removed
- Are pregnant or plan to become pregnant

**Females who are able to become pregnant:**

- Your healthcare provider should do a pregnancy test before you start treatment with Prolia®.
- You should use an effective method of birth control (contraception) during treatment with Prolia® and for at least 5 months after your last dose of Prolia®.
- Tell your doctor right away if you become pregnant while taking Prolia®.
- Are breast-feeding or plan to breast-feed

**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 women being treated for osteoporosis after menopause are back pain, pain in your arms and legs, high cholesterol, muscle pain, and bladder infection. The most common side effects of Prolia® in men with osteoporosis are back pain, joint pain, and common cold (runny nose or sore throat).

These are not all the possible side effects of Prolia®. 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](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

**Please see Prolia® full Prescribing Information and Medication Guide.**

