



INFORMED CONSENT FOR TREATMENT WITH PROLIA

Read the medication guide that comes with Prolia before you start taking it and each time you get a refill. There may be new information. This medication guide does not take the place of talking with your doctor about your medical condition or treatment. Talk to your doctor if you have any questions about Prolia.

What is Prolia?

Prolia is a prescription medicine used to treat osteoporosis (thinning and weakening of bone) in women after menopause (“change of life”) who:

- Have an increased risk for fractures (broken bones).
- Cannot use another osteoporosis medicine or other osteoporosis medicines did not work well.

What is osteoporosis?

Osteoporosis is a disease in which the bones become thin and weak, increasing the chance of having a broken bone. Osteoporosis usually causes no symptoms until a fracture happens

The following risk factors increase your chance of getting fractures from osteoporosis:

- Past broken bones from osteoporosis
- Very low bone mineral density (BMD)
- Frequent falls
- Limited movement, such as using a wheelchair
- Medical conditions likely to cause bone loss, such as some kinds of arthritis
- Taking steroid medicines called glucocorticoids, such as prednisone
- Other medicines that may cause bone loss, for example: seizure medicines (such as phenytoin), blood thinners (such as heparin), high doses of vitamin A

What can I do to treat osteoporosis?

There are many steps you can take to treat osteoporosis. Taking Prolia, along with calcium and vitamin D, may be one option for you.

Who should not receive Prolia?

Do not take Prolia if you have been told by your doctor that your blood calcium level is too low.

How will I receive Prolia?

- Prolia is an injection that will be given to you by a healthcare professional. Prolia is injected under your skin (subcutaneous).
- You will receive Prolia 1 time every 6 months.
- You should take calcium and vitamin D as your doctor tells you to while you receive Prolia.
- If you miss a dose of Prolia, you should receive your injection as soon as you can.

- Take good care of your teeth and gums while you receive Prolia. Brush and floss your teeth regularly.
- Tell your dentist that you are receiving Prolia before you have dental work.

What are the possible side effects of Prolia?

Prolia may cause serious side effects.

1. Low calcium levels in your blood (hypocalcemia).

Prolia may lower the calcium levels in your blood. If you have low blood calcium before you start receiving Prolia, it may get worse during treatment. Your low blood calcium must be treated before you receive Prolia. Most people with low blood calcium levels do not have symptoms, but some people may have symptoms. Call your doctor right away if you have symptoms of low blood calcium such as:

- Spasms, twitches, or cramps in your muscles
- Numbness or tingling in your fingers, toes, or around your mouth

Your doctor may prescribe calcium and vitamin D to help prevent low calcium levels in your blood while you take Prolia. Take calcium and vitamin D as your doctor tells you to.

2. Serious infections.

Prolia is a medicine that may weaken your immune system, thereby increasing risk of infections. Serious infections in your skin, abdomen, bladder, or ear may occur. Inflammation of the inner lining of the heart (endocarditis) due to an infection also may happen more often in people who take Prolia. You may need to go to the hospital for treatment if you develop an infection.

Call your doctor right away if you have any of the following symptoms of infection:

- Fever or chills
- Skin that looks red or swollen and is hot or tender to the touch
- Severe abdominal pain
- Frequent or urgent need to urinate or burning feeling when you urinate

3. Skin problems.

Skin problems such as inflammation of your skin (dermatitis), rash, and eczema may happen if you take Prolia. Call your doctor if you have any of the following symptoms of skin problems that do not go away or get worse:

- Redness
- Itching
- Small bumps or patches (rash)
- Your skin is dry or feels like leather
- Blisters that ooze or become crusty

4. Severe jaw bone problems (osteonecrosis).

Severe jaw bone problems may happen when you take Prolia. Your doctor should examine your mouth before you start Prolia. Your doctor may tell you to see your dentist before you start Prolia. It is important for you to practice good mouth care during treatment with Prolia.

5. **Long-term effects on bone:** It is not known if the use of Prolia over a long period of time may cause slow healing of broken bones or unusual fractures.
6. **Rebound fracture risk:** Prolia effect is not long lasting, the effect wears off in 6 months. Afterwards, if prolia is significantly delayed, then there can be rebound increased risk of fractures, especially vertebral fracture.

The most common side effects of Prolia are:

- Back pain
- Pain in your arms and legs
- High cholesterol
- Muscle pain
- Bladder infection

These are not all the possible side effects of Prolia. For more information, ask your doctor or pharmacist.

If you have any of the above side effects, call your doctor right away.

Before taking Prolia, tell your doctor if you:

- 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. Prolia may harm your unborn baby. Tell your doctor right away if you become pregnant while taking Prolia.
- Are breast-feeding or plan to breast-feed. It is not known if Prolia passes into your breast milk. You and your doctor should decide if you will take Prolia or breast-feed. You should not do both.

Tell your doctor about which medicines you take, including prescription and nonprescription drugs, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of medicines with you to show to your doctor or pharmacist when you get a new medicine.

How should I handle Prolia if I need to pick it up from a pharmacy?

- Keep Prolia in a refrigerator at 36°F to 46°F (2°C to 8°C) in the original carton
- Do not freeze Prolia
- When you remove Prolia from the refrigerator, Prolia must be kept at room temperature [up to 77°F (25°C)] in the original carton and must be used within 14 days
- Do not keep Prolia at temperatures above 77°F (25°C). Warm temperatures will affect how Prolia works
- Do not shake Prolia
- Keep Prolia in the original carton to protect from light

Keep Prolia and all medicines out of reach of children.

General information about Prolia

Do not give Prolia to other people even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about Prolia. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Prolia that is written for health professionals.

EMERGENCY CONTACTS:

In case of emergency, you can contact our office at (503) 297-3384 from 8:00 am to 5:00 pm Monday – Friday, or after hours dial the above number to page your physician or call 911 or go to the emergency room.

I certify that I have read and understand this consent form and agree to receive Prolia. I have had an opportunity to discuss this treatment with my physician and ask questions regarding the treatment. I will be given a signed copy of this form for my records.

Patient printed name

DOB

Patient signature

Date