

INFORMED CONSENT FOR TREATMENT WITH 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") where:

- There is an increased risk for fractures (broken bones).
- another 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 which are 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 once 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.

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 call your doctor right away if you have symptoms of low blood calcium such as spasms, twitches, 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 or go to the nearest emergency room 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, Itching, rash, blisters, dry leather like, severe abdominal pain, frequent or urgent need to urinate or burning feeling when you urinate

3. Severe jawbone problems (osteonecrosis)

Severe jawbone problems may happen when you take Prolia. You should see your dentist before starting Prolia. It is important for you to practice good mouth care during treatment with Prolia.

4. 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.

5. 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 fractures.

6. Other common side effects:

Back pain, high cholesterol, muscle pain

Before taking Prolia, tell your doctor if you:

- a. Have low blood calcium
- b. Cannot take daily calcium and vitamin D
- c. Had parathyroid or thyroid surgery (glands located in your neck)
- d. Have been told you have trouble absorbing minerals in your stomach or intestines (malabsorption syndrome)
- e. Have kidney problems or are on kidney dialysis
- f. Plan to have dental surgery or teeth removed
- g. 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.
- h. 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.

EMERGENCY CONTACTS:

In case of an emergency, please call 911 or go to the nearest emergency room. You can contact our office at (916) 677-4744 from 8:00 am to 5:00 pm Monday – Friday.

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 Name

Patient DOB

Patient Signature

Date

FINANCIAL RESPONSIBILITY:

Our office will contact your insurance company, and the necessary arrangements will be made for approval of the medication and administration. You may want to follow up with your insurance company also to be sure everything is covered. **Our office does NOT provide a guarantee of coverage for any of these services. If coverage is not provided, YOU WILL BE RESPONSIBLE for any charges incurred for treatment and/or follow-up care.**

Patient Signature

Date