Prolia® (denosumab) Guide for Patients: Important Things YOU Need to Know

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:
  - are at high risk for fracture (broken bone)
  - cannot use another osteoporosis medicine or other osteoporosis medicines did not work well
- Increase bone mass in men with osteoporosis who are at high risk for fracture
- 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
- Treat bone loss in women who are at high risk for fracture receiving certain treatments for breast cancer that has not spread to other parts of the body

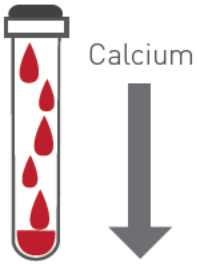
What side effects can Prolia® have?

Prolia® can cause serious side effects that all patients taking Prolia® must know.

Please talk about these side effects with your doctor.

Call your doctor right away if you think you may be having any of these side effects.

The side effects can include:

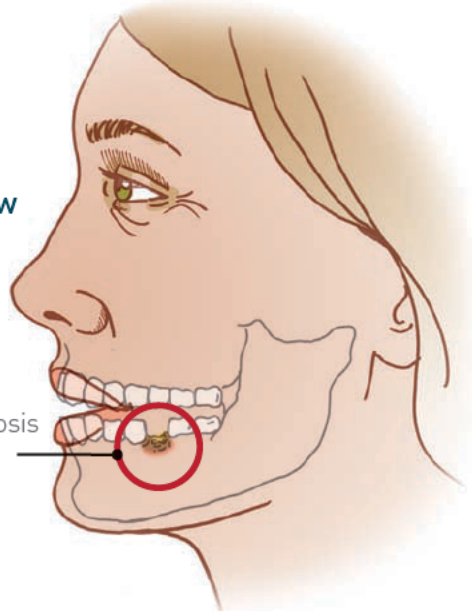


Low calcium levels in your blood

- Prolia® may lower the calcium levels in your blood
- Symptoms of low blood calcium include:
  - Spasms, twitches, or cramps in your muscles
  - Numbness or tingling in your fingers, toes, or around your mouth
- 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®
- 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

Severe jaw bone problems (osteonecrosis)

- Severe jaw bone problems (**o**steo**n**ecrosis of the **j**aw or ONJ) may happen when you take Prolia®
- ONJ is a potentially serious condition that can be seen as a sore in the mouth through which the jaw bone is sometimes visible. The jaw bone and gum tissue over the bone may heal slowly or not heal at all



Side effects are continued on back.

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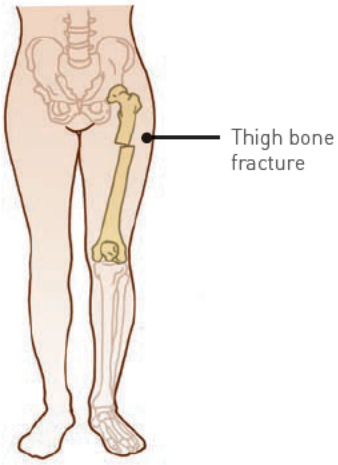
Severe jaw bone problems (osteonecrosis) cont.

- The most common risk factor associated with ONJ is tooth extraction. It is important for you to practice good mouth care during treatment with Prolia®
- See your dentist regularly for check-ups and cleaning
- Tell your dentist you are taking Prolia® or will start taking Prolia®

Unusual thigh fractures

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

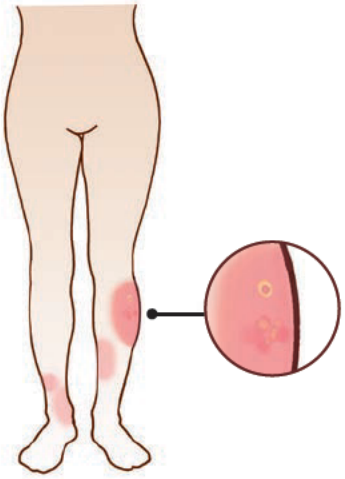


Serious infections

- Prolia® is a medicine that may affect the ability of your body to fight infections
- Serious infections in your skin, lower stomach area (abdomen), bladder, or ear may happen if you take Prolia®
- Inflammation of the inner lining of the heart (endocarditis) due to an infection also may happen more often in people who take Prolia®
- Symptoms of some serious infections include:
  - Fever or chills
  - Skin that looks red or swollen and is hot or tender to touch
  - Fever, shortness of breath, cough that will not go away
  - Frequent or urgent need to urinate or burning feeling when you urinate

Skin problems

- Skin problems may happen if you take Prolia®
- Symptoms of skin problems include:
  - Dermatitis (redness, itching)
  - Eczema (leathery dry skin, blisters that ooze or become crusty, skin peeling)



Call your doctor right away if you think you may be having any of these side effects.

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