

## Denosumab (Prolia)

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### About This Medicine

Denosumab (Prolia) is used to increase bone mass and strength in patients with a high risk for fracture due to cancer treatment. It is also used to treat osteoporosis. It is given as an injection under your skin (subcutaneously).

### Possible Side Effects

- Back pain
- Pain in your arms and/or legs
- Joint, muscle and bone pain
- Increase in your cholesterol level
- Effects on the bladder. This medicine may cause irritation and bleeding in the bladder. You may have blood in your urine.
- Inflammation of throat and nasal passages

**Note:** Each of the side effects above was reported in 5% or greater of patients treated with denosumab (Prolia). All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your medical team.

### Warnings and Precautions

- Allergic reactions, including anaphylaxis, are rare but may happen in some patients. Signs of allergic reaction to this medicine may be swelling of the face, feeling like your tongue or throat are swelling, trouble breathing, rash, itching, fever, chills, feeling dizzy, and/or feeling that your heart is beating in a fast or not normal way. **If this happens, do not take another dose of this medicine. You should get urgent medical treatment**
- Severe low calcium level in your blood
- Osteonecrosis of the jaw. This is a breakdown of the jawbone. It is a serious but rare health problem.
- Risk of femoral bone fractures
- Risk of vertebral (spinal) fractures when treatment is stopped, especially if you have a history of vertebral fractures. Do not stop treatment without first talking to your doctor.
- Risk of severe infections
- Rash

- Severe joint, muscle and bone pain

**Note:** Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your medical team

## Important Information

- Do not substitute or take at the same time as Xgeva, which is another brand of denosumab.
- Denosumab (Prolia) may cause other medicines that lower your immunity to be more harmful to your immune system. This may raise your risk of infection.
- Do not stop, skip or delay taking denosumab (Prolia) without first talking with your doctor, as this can increase your risk of breaking bones.
- Take calcium and vitamin D supplements as your doctor recommends to decrease your risk of low calcium.

## Treating Side Effects

- If you get a rash do not put anything on it unless your doctor or nurse says you may. Keep the area around the rash clean and dry. Ask your doctor for medicine if your rash bothers you.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.
- Get regular exercise, with your doctor's approval. If you feel too tired to exercise vigorously, try taking a short walk.
- Drink enough fluids to keep your urine pale yellow.
- Tell your dentist and/or oral surgeon that you are taking this medicine. You should not have major dental surgery while on this medicine. Talk to your doctor about any dental problems you may have before starting this medicine. You may need to see your dentist to have a dental exam and fix any dental problems before starting this medicine. Take good care of your teeth. Make sure you see your dentist for regular follow-up appointments.

## Food and Medicine Interactions

- There are no known interactions of denosumab (Prolia) with food.
- This medicine may interact with other medicines. Tell your doctor and pharmacist about all the prescription and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) that you are taking at this time. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.

## When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:



- Fever of 100.4° F (38° C) or higher
- Chills
- Extreme weakness that interferes with your daily activities
- Signs of infection: fever or chills, cough, trouble breathing, severe pain in your abdomen, difficulty urinating, burning or pain when you pass urine, redness and/or swelling of the skin
- A new rash and/or itching or a rash that is not relieved by prescribed medicines
- Pain that does not go away or is not relieved by prescribed medicines
- Pain when passing urine; blood in urine
- Decreased urine or difficulty urinating
- New hip, thigh or groin pain, or other unexplained bone pain
- Signs of allergic reaction: swelling of the face, feeling like your tongue or throat are swelling, trouble breathing, rash, itching, fever, chills, feeling dizzy, and/or feeling that your heart is beating in a fast or not normal way. **If this happens, call 911 for emergency care.**
- Signs of osteonecrosis of the jaw such as pain, swelling or infection of the gums, loose teeth, poor healing of the gums, numbness or the feeling that your jaw is heavy
- Signs of low calcium such as numbness or tingling around your mouth or in your hands and/or feet, muscle stiffness, twitching, spasms, or cramps
- If you think you may be pregnant

## Reproduction Warnings

- **Pregnancy warning:** This medicine can have harmful effects on the unborn baby. Women of child-bearing potential should use effective methods of birth control during your treatment and for at least 5 months after stopping treatment. Let your doctor know right away if you think you may be pregnant.
- **Breastfeeding warning:** It is not known if this medicine passes into breast milk. For this reason, women should not breastfeed during treatment because this medicine could enter the breast milk and cause harm to a breastfeeding baby. Women should talk to their doctor about the appropriate timing to start breastfeeding after treatment.
- **Fertility warning:** Fertility studies have not been done with this medicine. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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