

Denosumab (Prolia)

About This Drug

Denosumab is used to stop and treat bone problems and breaks due to bone metastasis from a solid tumor. It is also used to stop and 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 drug 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. Not all possible side effects are included above.

Warnings and Precautions

- Allergic reactions, including anaphylaxis are rare but may happen in some patients. Signs of allergic reaction to this drug 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 drug. You should get urgent medical treatment**
- Severe low calcium which can very rarely be life-threatening. You may experience numbness or tingling around your mouth or in your hands or feet. Other symptoms of low calcium are muscle stiffness, twitching, spasms, or cramps.
- Osteonecrosis of the jaw. This is a breakdown of the jawbone. It is a serious but rare health problem.
- Femoral bone fractures
- Risk of vertebral fractures once is treatment is complete
- Serious 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 may cause other drugs that lower your immunity to be more harmful to your immune system. This may raise your risk of infection.
- 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. If you feel too tired to exercise vigorously, try taking a short walk.
- Drink plenty of fluids (a minimum of eight glasses per day is recommended).
- Tell your cancer doctor if you have any problems with your teeth or jaw before you start this drug. It is important that your dentist knows that you are on this drug. Give your dentist and your cancer doctor each other's name and phone number so they may call each other if they have any questions.
- Brush and floss your teeth as directed.

Food and Drug Interactions

- There are no known interactions of denosumab with food.
- This drug 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
- Tiredness or extreme weakness that interferes with your daily activities



- A new rash 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
- 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 or feet. Other symptoms of low calcium are muscle stiffness, twitching, spasms, or cramps.
- If you think you may be pregnant or may have impregnated your partner

Reproduction Warnings

- **Pregnancy warning:** This drug can have harmful effects on the unborn baby. Women of child-bearing potential should use effective methods of birth control during your cancer treatment and for at least 5 months after treatment. Let your doctor know right away if you think you may be pregnant.
- **Breastfeeding warning:** It is not known if this drug passes into breast milk. For this reason, women should not breastfeed during treatment because this drug 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:** This drug is not expected to affect your ability to have children in the future. Human fertility studies have not been done with this drug.

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