

Denosumab (Prolia)-xxxx (Prolia, Jubbonti, Conexence, Osenvelt, Stoboclo, Ospomyv)

About This Medicine

DENOSUMAB (den oh SUE mab) prevents weakened bones caused by cancer. It may also be used to treat noncancerous bone tumors that cannot be removed by surgery. It can also be used to treat high calcium levels in the blood caused by cancer. It works by blocking a protein that causes bones to break down quickly. This slows down the release of calcium from bones, which lowers calcium levels in your blood. It also makes your bones stronger and less likely to break (fracture). It is given as an injection under your skin (subcutaneously).

This medicine may be used for other purposes; ask your care team if you have questions.

Possible Side Effects

- Back pain
- Pain in your arms and/or legs
- Joint, muscle and bone pain

Note: Each of the side effects above was reported in 10% or greater of people treated with denosumab (Prolia)-xxxx. 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 care team.

Warnings and Precautions

- Allergic reactions, including anaphylaxis, are rare but may happen in some people. 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, which can be life-threatening. This risk can be higher in people with kidney disease.
- 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 care team.

- 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 care team

Important Information

- Do not substitute or take at the same time as Xgeva or Wyost, which are other similar brand products of denosumab-xxxx.
- Denosumab (Prolia)-xxxx 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)-xxxx without first talking with your care team, as this can increase your risk of breaking bones.
- Take calcium and vitamin D supplements as your care team recommends to decrease your risk of low calcium.

Treating Side Effects

- If you get a rash do not put anything on it unless your care team says you may. Keep the area around the rash clean and dry. Ask your care team for medicine if your rash bothers you.
- Keeping your pain under control is important to your well-being. Please tell your care team if you are experiencing pain.
- Get regular exercise, with your care team's approval. If you feel too tired to exercise vigorously, try taking a short walk.
- 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 care team 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)-xxxx with food.
- This medicine may interact with other medicines. Tell your care team 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 care team before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.

When to Call Your Care Team



Call your care team 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
- 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

Reproduction Warnings

- **Pregnancy warning:** This medicine can cause serious birth defects. If you can become pregnant, use birth control while taking this medicine and for 5 months after the last dose. Tell your care team right away if you think you might be pregnant.
- **Breastfeeding warning:** Talk with your care team about breastfeeding during treatment. You may need to stop breastfeeding.

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