About Prolia® - Denosumab

Denosumab is a type of monoclonal antibody. It is a medicine designed to target a specific protein or cell – in this case, the target is a protein called RANKL, which helps the formation, function, and survival of osteoclasts that help with bone resorption. By targeting RANKL, bone resorption is decreased and bone mass and strength are increased.

Denosumab (Prolia®) is used to treat osteoporosis in postmenopausal women, increase bone mass in men with osteoporosis, glucocorticoid-induced osteoporosis, in men receiving androgen deprivation therapy for prostate cancer, and for women taking aromatase inhibitor therapy. This medication is different from Denosumab (Xgeva®) which treats bone metastasis. They are used to treat different issues, are not interchangeable, and also should not be taken at the same time.

How to Take Denosumab (Prolia®)

Denosumab (Prolia®) is usually given every 6 months by subcutaneous injection (SQ, given under the skin) in the upper arm, upper thigh, or abdomen. You may need to take calcium and vitamin D supplements to help with your bone health and prevent your blood calcium levels from getting too low. If you miss a dose, schedule your missed dose as soon as possible. Latex can be found in the gray needle caps of some single-dose prefilled syringes, so you should let your provider know if you are allergic to latex. If you are allergic to latex you should not handle the cap.

Possible Side Effects of Denosumab (Prolia®)

There are a number of things you can do to manage the side effects of denosumab (Prolia®). Talk to your doctor or nurse about these recommendations. They can help you decide what will work best for you. These are some of the most common side effects:

Pain

Patients taking this medication may have pain in their back and other parts of their body. Talk to your provider about how you can manage this pain.

Less common, but important side effects can include:

- **Low Blood Calcium (Hypocalcemia):** This medication can cause your blood calcium levels to drop below normal. Calcium and vitamin D supplements can be taken to prevent the level from getting too low. Signs that calcium levels are low include numbness or tingling sensation around the lips, muscle stiffness, twitching, spasms or cramps. Be sure to notify your oncology team if these symptoms occur.
- **Allergic Reactions:** In some cases, patients can have an allergic reaction to this medication. Signs of a reaction can include: decreased blood pressure, shortness of breath, lip swelling, rash, itching, and hives. If you notice any changes in how you feel during or after the injection, let your healthcare team know immediately.
- **Osteonecrosis of the Jaw:** Osteonecrosis of the jaw (ONJ) is a rare side effect, however, it is important that you know about it and take steps to protect your dental health. The maxilla (upper jaw bone) and mandible (lower jaw bone) are normally covered by gum tissue. In the case of ONJ, this tissue is gone and the bone is exposed. Typical symptoms associated with ONJ are pain, swelling or infection of the gums, loosening of the teeth, exposed bone (often at the site of
a previous tooth extraction). Some patients may report numbness or tingling in the jaw or a "heavy" feeling jaw. ONJ may have no symptoms for weeks or months and may only be recognized by the presence of exposed bone. ONJ most often occurs soon after a dental procedure, though not always. Ask your provider how long you need to stop taking this medication before having an invasive dental procedure.

- Prior to starting therapy, you should have a complete dental exam, cleaning, and removal of any teeth in poor health.
- Dentures should be checked for proper fit.
- Brush your teeth after meals and at bedtime with a soft brush. Floss gently once a day. If your gums bleed, talk with your healthcare team to see if you can continue to floss.
- Check your teeth and gums in a mirror daily for any sores, swelling, loose teeth, pain or numbness, or other changes, and report these to your dentist or oncology team immediately.

- **Bone Fractures:** This medication can increase your risk of bone fractures, especially of the femur (thigh) and spine. If you have any new or unusual thigh, hip, groin, or back pain, contact your provider right away.

- **Vertebral Fracture (broken bones in the spine):** You may be at higher risk for fractures in the spine when this medicine is stopped, especially if you have a history of osteoporosis or other fractures. Report any new or worsening back pain to your healthcare team. Do not stop the medication without talking to your provider.

- **Infection:** This medication can cause infections of the skin, abdomen, bladder, and ear. This medication can also lower your ability to fight infections. If you have a fever, chills, skin that is red, swollen, hot, or tender to the touch, shortness of breath or a cough that won’t go away, belly pain, or frequency and urgency with urinating, you should contact your provider right away.

- **Skin Reactions:** This medication can cause skin reactions like rashes, dermatitis, and eczema. If you have new redness, itching, small bumps or patches, skin is drier than normal or becomes leathery, blisters that crust or ooze, or your skin is peeling, contact your provider right away.

**Reproductive Concerns**

Exposure of an unborn child to this medication could cause birth defects, so you should not become pregnant or father a child while on this medication. Effective birth control is necessary during treatment and for 5 months after treatment. Even if your menstrual cycle stops or you believe you are not producing sperm, you could still be fertile and conceive. You should consult with your healthcare team before breastfeeding while receiving this medication.

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