



## Xgeva® - Denosumab

**Pronounce:** den-OH-sue-mab

**Classification:** Monoclonal Antibody

### About Xgeva® - Denosumab

Cancer cells from some tumors (most commonly breast, prostate and lung cancers) can spread to the bone. When this happens, it is called bone metastasis. Cancer cells in the bone can cause breakdown or wearing away of normal bone. In turn, the affected bones become more fragile. They may be painful and can even break due to the damage from the cancer cells. 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 is necessary for bone breakdown. By targeting RANKL, denosumab inhibits or stops bone breakdown.

Monoclonal antibodies are created in a lab to attach to the targets found on specific types of cancer cells. The antibody “calls” the immune system to attack the cell it is attached to, resulting in the immune system killing the cell. These antibodies can work in different ways, including stimulating the immune system to kill the cell, blocking cell growth, or other functions necessary for cell growth. This medication is different from [Denosumab \(Prolia®\)](#) which treats osteoporosis. They are used to treat different issues, are not interchangeable, and also should not be taken at the same time.

### How to Take Denosumab (Xgeva®)

Denosumab (Xgeva®) is usually given every 4 weeks by subcutaneous injection (SQ, given under the skin, similar to insulin). Your healthcare provider may have you take calcium and vitamin D supplements to help with your bone health and prevent your blood calcium levels from getting too low. Talk with your team about what doses are right for you. You should drink plenty of fluids while taking this medication. Try to drink 8-10 glasses of non-alcoholic, non-caffeinated liquids a day.

### Possible Side Effects of Denosumab (Xgeva®)

There are a number of things you can do to manage the side effects of denosumab. 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:

#### Fatigue and Weakness

[Fatigue](#) is very common during cancer treatment and is an overwhelming feeling of exhaustion and weakness that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage these side effects. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

#### Electrolyte Abnormalities

This medication can affect the normal levels of electrolytes (phosphorus) in your body. Your levels will be monitored using blood tests. If your levels become too low, your care team may prescribe specific electrolytes to be given by IV or taken by mouth. Do not take any supplements without first consulting with your care team.

## Nausea and/or Vomiting

Talk to your oncology care team so they can prescribe medications to help you manage [nausea and vomiting](#). In addition, dietary changes may help. Avoid things that may worsen the symptoms, such as heavy or greasy/fatty, spicy or acidic foods (lemons, tomatoes, oranges). Try saltines, or ginger ale to lessen symptoms.

Call your oncology care team if you are unable to keep fluids down for more than 12 hours or if you feel lightheaded or dizzy at any time.

## Shortness of Breath

This medication can cause shortness of breath. If you have sudden shortness of breath or chest pain, call 911 or go to the Emergency Room right away.

## Constipation

There are several things you can do to prevent or relieve constipation. Include fiber in your diet (fruits and vegetables), drink 8-10 glasses of non-alcoholic fluids a day, and keep active. A stool softener once or twice a day may prevent constipation. If you do not have a bowel movement for 2-3 days, you should contact your healthcare team for [suggestions to relieve the constipation](#).

## Low Red Blood Cell Count (Anemia)

Your red blood cells are responsible for carrying oxygen to the tissues in your body. When the [red cell count is low](#), you may feel tired or weak. You should let your oncology care team know if you experience any shortness of breath, difficulty breathing or pain in your chest. If the count gets too low, you may receive a blood transfusion.

## Diarrhea

Your oncology care team can recommend medications to relieve [diarrhea](#). Also, try eating [low-fiber](#), bland foods, such as white rice and boiled or baked chicken. Avoid raw fruits, vegetables, whole-grain breads, cereals, and seeds. Soluble fiber is found in some foods and absorbs fluid, which can help relieve diarrhea. Foods high in soluble fiber include: applesauce, bananas (ripe), canned fruit, orange sections, boiled potatoes, white rice, products made with white flour, oatmeal, cream of rice, cream of wheat, and farina. Drink 8-10 glasses of non-alcoholic, un-caffeinated fluid a day to prevent dehydration.

## Important but Less Common Side Effects

- **Low Blood Calcium (Hypocalcemia):** Denosumab (Xgeva®) 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. Stop treatment with denosumab

(Xgeva®) at least 3 weeks prior to any dental procedures.

- 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.
- **Femur (Thigh Bone) Fracture:** This medication can cause atypical femoral fractures (thigh bone) with minimal or no trauma contributing to the fracture. If you experience new or unusual thigh, hip, or groin pain, contact your healthcare team immediately.
- **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.

## 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 for women. 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.

## Current Biosimilars

There are biosimilar versions of denosumab. A biosimilar is a medication that the FDA has approved because it is very similar to an FDA-approved medication (called a reference product, or the medication it is being compared to). There are no meaningful differences between the biosimilar product and the reference product. These medications may be used interchangeably.

The biosimilar versions of this medication include Wyost (denosumab-bbdz), Bomynta (denosumab-bnht), Stobloco (denosumab-bmwo), Osenvelt (denosumab-bmwo), and Xbryk (denosumab-dssb).

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