

Prolia

Generic name: Denosumab

Trade names: Prolia[®], Xgeva[®]

Denosumab is the generic name for the trade name drugs Prolia[®] or Xgeva[®]. In some cases, health care professionals may use the trade names Prolia[®] or Xgeva[®] when referring to the generic drug name denosumab. Prolia[®] and Xgeva[®] are the same generic drug (denosumab). They were given distinct trade names in order to differentiate between their unique dosing schedules and indications for use. How they are used is different, but strictly speaking, the two are the same drug.

Drug type:

Prolia is a monoclonal antibody that works as a RANK ligand (RANKL) inhibitor. This medication is classified as a "bone-modifying agent". (For more detail see "How denosumab works" section below).

What Prolia Is Used For:

- **Prolia**
 - Treatment of postmenopausal women with osteoporosis at high risk for fracture.
 - Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer.
 - Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

Note: If a drug has been approved for one use, physicians sometimes elect to use this same drug for other problems if they believe it might be helpful.

How Prolia Is Given:

- As a subcutaneous injection in the upper arm, upper thigh, or abdomen. A subcutaneous injection is a shot into the layer of skin directly below the outer skin layer.
- There is no pill form of Prolia.
- The amount of Prolia you will receive depends on many factors, including your general health or other health problems, and the type of cancer or condition you have. Your doctor will determine your dose and schedule.

Side Effects:

Important things to remember about the side effects of Prolia:

- Most people will not experience all of the denosumab side effects listed.
- Prolia side effects are often predictable in terms of their onset, duration and severity.
- Prolia side effects will likely improve after therapy is complete.
- Prolia side effects may be quite manageable. There are many options to minimize or prevent the side effects of Prolia.

The following are common (occurring in greater than 30%) side effects for patients taking Prolia:

- Fatigue
- Muscle weakness
- Decreased levels of phosphorus in your blood (hypophosphatemia)
- Nausea

These are less common side effects (occurring in 10-29%) for patients receiving Prolia:

- Diarrhea
- Shortness of breath
- Low levels of calcium in your blood (hypocalcemia).
- Cough
- Joint pain
- Headache
- Limb pain
- Back pain
- Eczema (a skin condition that may include any of the following: redness, skin swelling, itching and dryness, crusting, blistering or bleeding).

- Rash

Osteonecrosis of the jaw has been reported rarely in patients with cancer receiving treatment regimens that include bone modifying agents. Many of the reported cases were associated with dental procedures, such as removal of a tooth. A dental examination with appropriate preventative dentistry should be considered prior to treatment with denosumab, particularly in patients with additional risk factors (ie cancer, chemotherapy, corticosteroids, poor oral hygiene). **Invasive dental procedures should be avoided during treatment.**

Not all side effects are listed above, some that are rare (occurring in less than 10% of patients) are not listed here. However, you should always inform your health care provider if you experience any unusual symptoms.

When to contact your doctor or health care provider:

Contact your health care provider *immediately*, day or night, if you should experience the following:

- Difficulty breathing
- Chest pain
- Swelling of the face/throat
- Confusion

The following symptoms require medical attention, but are not an emergency. Contact your health care provider *within 24 hours* after noticing any of the following:

- Muscle stiffness, twitching, spasms, or cramps (signs of low blood calcium)
- Pain, numbness, swelling of or drainage from the jaw, mouth or teeth.
- Any signs or symptoms of infection, especially involving the skin (redness, drainage, pain)
- Fever of 100.4° F (38° C)
- Fatigue and extreme tiredness (unable to perform self-care activities)
- Nausea that interferes with eating and is not relieved by medications prescribed by your doctor.
- Vomiting (more than 4-5 episodes within a 24-hour period).

Always inform your health care provider if you experience any unusual symptoms.

Precautions:

- Do not use both Xgeva and Prolia at the same time. If you are receiving one, you should not be receiving the other, too.
- Before starting Prolia treatment, make sure you tell your doctor about any other medications you are taking (including over-the-counter drugs, vitamins, or herbal remedies). Do not take aspirin or products containing aspirin unless your doctor permits this.
- Prolia may enhance the negative effects of immuno-suppressants. Specifically, the risk for serious infections may be increased. Notify your doctor of any immuno-suppressive medication you are taking.
- Do not receive any kind of vaccination without your doctor's approval while taking Prolia.
- Inform your health care professional if you are pregnant or may be pregnant prior to starting this treatment. Pregnancy category C (use in pregnancy only if benefit to mother outweighs risk to fetus).
- For both men and women: Do not conceive a child (get pregnant) while taking Prolia. Barrier methods of contraception, such as condoms, are recommended.
- It is not known whether Prolia is excreted into human milk. Because of the potential for serious adverse reactions in nursing infants from Prolia, a decision should be made whether to discontinue nursing or discontinue the drug taking into account the importance of the drug to the mother.

Self-Care Tips:

- Take a calcium and vitamin D supplement as necessary to treat and/or prevent low blood calcium levels. Go for blood tests as ordered by your provider.
- Perform proper, thorough oral hygiene and routine dental care. Inform your dentist that you are being treated with Prolia.
- Avoid invasive dental procedures.
- Inform your physician or dentist if you experience persistent pain and/or slow healing of the mouth or jaw following invasive dental procedures.
- Drink at least 2 to 3 quarts of fluid every 24 hours, unless you are instructed otherwise, as it is important to avoid becoming dehydrated.
- Acetaminophen may help relieve discomfort from fever, headache and generalized aches and pains, however talk with your provider prior to taking it.
- To reduce nausea, take anti-nausea medications as prescribed by your doctor, and eat small, frequent meals.

- Eat foods that may help reduce diarrhea (see managing side effects - diarrhea) and if necessary, follow the regimen of anti-diarrhea medication as prescribed by your health care professional.
- Use mild, unscented soaps, laundry detergents, and lotions to avoid irritating your skin. Use lotion liberally to keep skin moisturized and prevent cracking. (see managing side effects - dry skin)
- Get plenty of rest.
- Maintain good nutrition.
- If you experience symptoms or side effects, be sure to discuss them with your health care team. They can prescribe medications and/or offer other suggestions that are effective in managing such problems.

Monitoring and Testing:

You will be checked regularly by your doctor while you are taking Prolia, to monitor side effects and check your response to therapy. Periodic blood work will be obtained to monitor the function of your organs (such as your kidneys and liver), as deemed necessary by your doctor.

How Prolia Works:

Cancer cells that spread to the bone can secrete substances that can cause cells in the bone called osteoclasts to dissolve or "eat away" a portion of the bone. The process, during which osteoclasts break down bone and then release those minerals such as calcium from bone fluid into the blood, is called "bone resorption". These tumors or lesions in the bone weaken the bone and can lead to complications, referred to as "skeletal related events". Some of the complications (skeletal related events) that can result from this bone breakdown are bone pain, fractures, and the need for additional procedures such as radiation therapy to reduce pain or surgery to fix or stabilize an affected bone. Bone resorption also releases growth factors that may cause growth of tumors.

Receptor activator of nuclear factor kappa-B ligand (RANKL) is a type of protein that is important in bone metabolism. This natural and necessary protein is found on osteoblasts (cells that are responsible for bone formation) and serves to activate osteoclasts (cells involved in bone resorption - as described above). By inhibiting RANKL we may be able to decrease bone resorption and therefore decrease bone loss and hypercalcemia.

Prolia binds to RANKL, a protein that is essential for the formation, function and survival of osteoclasts, the cells responsible for bone resorption. Prolia inhibits osteoclast formation, function and survival thereby, decreasing bone resorption and increasing bone mass and strength of the bone.

Note: We strongly encourage you to talk with your health care professional about your specific medical condition and treatments. The information contained in this website is meant to be helpful and educational, but is not a substitute for medical advice.

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