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## Denosumab Injection

pronounced as (den oh' sue mab)

### Why is this medication prescribed?

#### Denosumab injection (Prolia) is used

- to treat osteoporosis (a condition in which the bones become thin and weak and break easily) in women who have undergone menopause ("change of life;" end of menstrual periods) who have an increased risk for fractures (broken bones) or who cannot take or did not respond to other medication treatments for osteoporosis.
- to treat men who have an increased risk for fractures (broken bones) or who cannot take or did not respond to other medication treatments for osteoporosis.
- treat osteoporosis that is caused by corticosteroid medications in men and women who will be taking corticosteroid medications for at least 6 months and have an increased risk for fractures or who cannot take or did not respond to other medication treatments for osteoporosis.
- to treat bone loss in men who are being treated for prostate cancer with certain medications that cause bone loss,
- to treat bone loss in women with breast cancer who are receiving certain medications that increase their risk for fractures.

**Denosumab injection (Xgeva) is used Denosumab injection is in a class of medications called RANK ligand inhibitors. It works to prevent bone loss by blocking a certain receptor in the body to decrease bone breakdown. It works to treat GCTB by blocking a certain receptor in the tumor cells which slows the tumor growth. It works to treat high calcium levels by decreasing bone breakdown as the breakdown of bones releases calcium.**

- to reduce the risk of fractures in people who have multiple myeloma (cancer that begins in the plasma cells and causes bone damage), and in people who have certain types of cancer that began in another part of the body but has spread to the bones.
- in adults and some adolescents to treat giant cell tumor of bone (GCTB; a type of bone tumor) that cannot be treated with surgery.
- to treat high calcium levels that are caused by cancer in people who did not respond to other medications.

### How should this medicine be used?

Denosumab injection comes as a solution (liquid) to be injected subcutaneously (under the skin) in your upper arm, upper thigh, or stomach area. It is usually injected by a doctor or nurse in a medical office or clinic. Denosumab injection (Prolia) is usually given once every 6 months. When denosumab injection (Xgeva) is used to reduce the risk of fractures from multiple myeloma, or cancer that has spread to the bones, it is usually given once every 4 weeks. When denosumab injection (Xgeva) is used to treat giant cell tumor of bone, or high calcium levels caused by cancer, it is usually given every 7 days for the first three doses (on day 1, day 8, and day 15) and then once every 4 weeks starting 2 weeks after the first three doses.

Your doctor will tell you to take supplements of calcium and vitamin D while you are being treated with denosumab injection. Take these supplements exactly as directed.

When denosumab injection (Prolia) is used to treat osteoporosis or bone loss, your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with denosumab injection and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>] ) or the manufacturer's website to obtain the Medication Guide.

## Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

## What special precautions should I follow?

### Before receiving denosumab injection,

- tell your doctor and pharmacist if you are allergic to denosumab (Prolia, Xgeva), any other medications, latex, or any of the ingredients in denosumab injection. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- you should know that denosumab injection is available under the brand names Prolia and Xgeva. You should not receive more than one product containing denosumab at the same time. Be sure to tell your doctor if you are being treated with either of these medications.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: angiogenesis inhibitors such as axitinib (Inlyta), bevacizumab (Avastin), everolimus (Afinitor, Zortress), pazopanib (Votrient), sorafenib (Nexavar), or sunitinib (Sutent); bisphosphonates such as alendronate (Binosto, Fosamax), etidronate, ibandronate (Boniva), pamidronate, risedronate (Actonel, Atelvia), zoledronic acid (Reclast); cancer chemotherapy medications; medications that suppress the immune system such as azathioprine (Azasan, Imuran), cyclosporine (Gengraf, Neoral, Sandimmune), methotrexate (Otrexup, Rasuvo, Trexall, Xatmep), sirolimus (Rapamune), and tacrolimus (Astagraf XL, Envarsus, Prograf); steroids such as dexamethasone, methylprednisolone (A-Methapred, Depo-Medrol, Medrol, Solu-Medrol), and prednisone (Rayos); or medications used to lower your calcium levels, such as cinacalcet (Sensipar). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have or have ever had a low level of calcium in your blood. Your doctor will probably check the level of calcium in your blood before you begin treatment and will probably tell

you not to receive denosumab injection if the level is too low.

- tell your doctor if you are receiving dialysis treatments or if you have or have ever had anemia (condition in which the red blood cells do not bring enough oxygen to all the parts of the body); cancer; any type of infection, especially in your mouth; problems with your mouth, teeth, gums, or dentures; dental or oral surgery (teeth removed, dental implants); any condition that stops your blood from clotting normally; any condition that decreases functioning of your immune system; surgery on your thyroid gland or parathyroid gland (small gland in the neck); surgery to remove part of your small intestine; problems with your stomach or intestine that make it difficult for your body to absorb nutrients; polymyalgia rheumatica (disorder that causes muscle pain and weakness); diabetes, or parathyroid or kidney disease.
- tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding. You will need to have a negative pregnancy test before starting treatment with denosumab injection. You should not become pregnant while you are receiving denosumab injection. You should use a reliable method of birth control to prevent pregnancy while you are receiving denosumab injection and for at least 5 months after your final treatment. If you become pregnant while receiving denosumab injection, or within 5 months of your treatment, call your doctor immediately. Denosumab may harm the fetus.
- you should know that denosumab injection may cause osteonecrosis of the jaw (ONJ, a serious condition of the jaw bone), especially if you have dental surgery or treatment while you are receiving this medication. A dentist should examine your teeth and perform any needed treatments, including cleaning or fixing ill-fitted dentures, before you start to receive denosumab injection. Be sure to brush your teeth and clean your mouth properly while you are receiving denosumab injection. Talk to your doctor before having any dental treatments while you are receiving this medication.

## What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

## What should I do if I forget a dose?

If you miss an appointment to receive an injection of denosumab, you should call your healthcare provider as soon as possible. The missed dose should be given as soon as it can be rescheduled. When denosumab injection (Prolia) is used for osteoporosis or bone loss, after you receive the missed dose, your next injection should be scheduled 6 months from the date of your last injection.

## What side effects can this medication cause?

**Denosumab injection may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:**

- red, dry, or itchy skin
- oozing or crusty blisters on skin
- peeling skin
- back pain
- pain in your arms
- swelling of arms or legs
- muscle or joint pain

- nausea
- diarrhea
- constipation
- abdominal pain
- headache

**Some side effects can be serious. If you experience any of these symptoms, call your doctor immediately or get emergency medical treatment:**

- muscle stiffness, twitching, cramps, or spasms
- numbness or tingling in your fingers, toes, or around your mouth
- hives, rash, itching, difficulty breathing or swallowing, swelling of the face, eyes, throat, tongue or lips,
- fever or chills
- redness, tenderness, swelling or warmth of area of skin
- fever, cough, shortness of breath
- ear drainage or severe ear pain
- frequent or urgent need to urinate, burning feeling when you urinate
- severe abdominal pain
- painful or swollen gums, loosening of the teeth, numbness or heavy feeling in the jaw, poor healing of the jaw
- unusual bleeding or bruising
- nausea, vomiting, headache, and decreased alertness after stopping denosumab and for up to 1 year afterwards

Denosumab injection may increase the risk that you will break your thigh bone(s) You may feel pain in your hips, groin, or thighs for several weeks or months before the bone(s) break, and you may find that one or both of your thigh bones have broken even though you have not fallen or experienced other trauma. It is unusual for the thigh bone to break in healthy people, but people who have osteoporosis may break this bone even if they do not receive denosumab injection. Denosumab injection may also cause broken bones to heal slowly and may impair bone growth and prevent teeth from coming in properly in children. Talk to your doctor about the risks of receiving denosumab injection.

Denosumab injection may cause other side effects. Call your doctor if you have any unusual problems while receiving this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>] ) or by phone (1-800-332-1088).

## What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Do not shake denosumab injection. Store it in the refrigerator and protect it from light. Do not freeze. Denosumab injection can be kept at room temperature for up to 14 days.

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

## What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain tests to be sure it is safe for you to receive denosumab injection and to check your body's response to denosumab injection.

Do not let anyone else use your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

## Brand names

- Prolia<sup>®</sup>
- Xgeva<sup>®</sup>

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