

Drug : **PROLIA INJ**

**What is this medicine?**

DENOSUMAB (den oh sue mab) slows bone breakdown. Prolia is used to treat osteoporosis in women after menopause and in men. Xgeva is used to prevent bone fractures and other bone problems caused by cancer bone metastases. Xgeva is also used to treat giant cell tumor of the bone.

**This medicine may be used for other purposes; ask your health care provider or pharmacist if you have questions.**

**What should I tell my health care provider before I take this medicine?**

They need to know if you have any of these conditions: -dental disease -eczema -infection or history of infections -kidney disease or on dialysis -low blood calcium or vitamin D -malabsorption syndrome -scheduled to have surgery or tooth extraction -taking medicine that contains denosumab -thyroid or parathyroid disease -an unusual reaction to denosumab, other medicines, foods, dyes, or preservatives -pregnant or trying to get pregnant -breast-feeding

**How should I use this medicine?**

This medicine is for injection under the skin. It is given by a health care professional in a hospital or clinic setting. If you are getting Prolia, a special MedGuide will be given to you by the pharmacist with each prescription and refill. Be sure to read this information carefully each time. For Prolia, talk to your pediatrician regarding the use of this medicine in children. Special care may be needed. For Xgeva, talk to your pediatrician regarding the use of this medicine in children. While this drug may be prescribed for children as young as 13 years for selected conditions, precautions do apply.

**Overdosage: If you think you have taken too much of this medicine contact a poison control center or emergency room at once.**

**NOTE: This medicine is only for you. Do not share this medicine with others.**

**What if I miss a dose?**

It is important not to miss your dose. Call your doctor or health care professional if you are unable to keep an appointment.

**Where should I keep my medicine?**

This medicine is only given in a clinic, doctor's office, or other health care setting and will not be stored at home.

**NOTE: This sheet is a summary. It may not cover all possible information. If you have questions about this medicine, talk to your doctor, pharmacist, or health care provider.**

**What should I watch for while using this medicine?**

Visit your doctor or health care professional for regular checks on your progress. Your doctor or health care professional may order blood tests and other tests to see how you are doing. Call your doctor or health care professional if you get a cold or other infection while receiving this medicine. Do not treat yourself. This medicine may decrease your body's ability to fight infection. You should make sure you get enough calcium and vitamin D while you are taking this medicine, unless your doctor tells you not to. Discuss the foods you eat and the vitamins you take with your health care professional. See your dentist regularly. Brush and floss your teeth as directed. Before you have any dental work done, tell your dentist you are receiving this medicine. Do not become pregnant while taking this medicine or for 5 months after stopping it. Women should inform their doctor if they wish to become pregnant or think they might be pregnant. There is a potential for serious side effects to an unborn child. Talk to your health care professional or pharmacist for more information.

**What side effects may I notice from receiving this medicine?**

Side effects that you should report to your doctor or health care professional as soon as possible: -allergic reactions like skin rash, itching or hives, swelling of the face, lips, or tongue -breathing problems -chest pain -fast, irregular heartbeat -feeling faint or lightheaded, falls -fever, chills, or any other sign of infection -muscle spasms, tightening, or twitches -numbness or tingling -skin blisters or bumps, or is dry, peels, or red -slow healing or unexplained pain in the mouth or jaw -unusual

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bleeding or bruising Side effects that usually do not require medical attention (Report these to your doctor or health care professional if they continue or are bothersome.): -muscle pain -stomach upset, gas

**This list may not describe all possible side effects. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.**

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