

Understanding Prolia®

Your doctor has prescribed Prolia. Here are some answers to common questions you may have about your treatment.



What is Prolia?

Prolia is an osteoporosis treatment for women after menopause who have an increased risk for fractures or cannot use other osteoporosis medication or for whom other osteoporosis medications did not work well. Prolia is also used to increase bone mass in men with osteoporosis at high risk for fracture.

How does Prolia work?

Bones are constantly changing. Normally, there is a balance between cells removing old bone and those creating new bone. With osteoporosis, more bone is removed than is replaced, resulting in bone loss. Your bones are thinner, weaker and more likely to break.

Prolia works by blocking RANK ligand, a protein that activates the cells that break down bone. By doing this, Prolia helps increase bone mass – making your bones stronger and lowering your chance of breaking your hip, spine and nonspinal sites.

Does Prolia cause any side effects?

Like all medications, Prolia can cause side effects although not everybody gets them. Possible side effects include:

- Pain, sometimes severe, in the muscles, joints, arms, legs or back
- Low blood calcium levels. Tell your doctor if you experience symptoms that may include muscle spasms, twitches, cramps, numbness or tingling in hands, feet or around the mouth, and weakness. Low blood calcium levels were reported in greater than or equal to 0.01% and less than 0.1% of patients taking Prolia
- Skin condition with itching, redness and/or dryness (eczema). This was reported in 1% to 10% of patients taking Prolia. Injection site reactions were uncommon
- Rash that may occur on the skin or sores in the mouth (lichenoid drug eruption)
- Allergic reactions (e.g. rash, hives, or in rare cases, swelling of the face, lips, tongue, throat or trouble breathing)
- Tell your doctor right away if you experience the symptoms of skin infection – swollen, red area of skin that feels hot and tender and may be accompanied by fever (cellulitis)
- Common cold (runny nose or sore throat)
- Broken bones in the spine after stopping Prolia (multiple vertebral fractures)
- Hair loss (alopecia)

Tell your doctor right away if you have:

Skin that looks red, swollen, hot or tender to touch. Infection may be accompanied by fever (cellulitis).

Frequent or urgent need to urinate or burning feeling when you urinate (bladder infection)

Severe stomach pains (pancreatitis)

Ear infection

Fever or chills (infection)

Sore in mouth involving gums or jaw bones (osteonecrosis of the jaw). Stop taking drug and call your doctor or pharmacist.

Endocarditis (inflammation of the inner lining of the heart). Stop taking drug and call your doctor or pharmacist.

Allergic reaction (feeling faint, trouble breathing/wheezing, throat tightness, swelling of face, lips or tongue, rash, hives). Stop taking drug and call your doctor or pharmacist.

Alert your doctor if you have:

Any of these skin problems that do not go away or worsen: redness; itching; rash; dry or leathery skin; open, crusted or peeling skin; blisters

New or unusual pain in your hip, groin or thigh (fracture of the thigh bone)

These are not all the possible symptoms or side effects that you may experience – it is important to contact your doctor or pharmacist if you are concerned about potential side effects you may be experiencing with your Prolia treatment.

After your treatment with Prolia is stopped, it is possible that broken bones in your spine may occur especially if you have a history of broken bones in the spine. Do not stop taking Prolia without first talking with your doctor. If your Prolia treatment is stopped, discuss other available treatment options with your doctor.

When and how should I take Prolia?

It is important to receive your Prolia injection every 6 months and to follow your doctor's instructions for calcium and vitamin D supplementation. Eating a well-balanced diet will help your calcium intake.



Prolia is taken as an injection just under the skin in your upper arm, upper thigh or abdomen. It can be given to you by a healthcare professional or a trained injector at any time of day, with or without food.



Start and stay with the proVital® Support Program

How will I remember to take Prolia? How will I stay on track?

The ProVital Support Program will help you start and stay on track with your Prolia treatment. As a member of the program, you will receive ongoing communications to help you learn about osteoporosis and manage your Prolia appointments.

Services include:

- Access to the ProVital Support Program via telephone and support to answer any questions you may have about Prolia, your drug plan coverage or monthly payment options
- Next injection reminders
- Newsletter series that is educational and helps keep you on track with the Program

You can also ask your doctor for the reminder card with calendar stickers that also come inside the box of Prolia to help you remember your next appointment.

How do I enrol in the ProVital Support Program?

- Call the toll-free number: 1-877-776-1002 from 8:00 a.m. to 8:00 p.m. EST, Monday to Friday.

Where can I find more information?

Prolia.ca is your online resource for more information on Prolia and postmenopausal osteoporosis. You can get answers to frequently asked questions and what you can expect from your treatment.

Visit Prolia.ca or call 1-877-776-1002 to enrol today!



For complete information, please refer to the Prolia Consumer Information section of the Prolia Product Monograph or package insert. To obtain a copy of the full Product Monograph, prepared for health professionals, call the ProVital Support Program information line toll-free at 1-877-776-1002 or visit www.prolia.ca [DIN 02343541].

You should not use Prolia if you: Are allergic to denosumab or any other ingredient of Prolia; have low calcium levels in your blood (hypocalcemia); are less than 18 years of age; are pregnant or breastfeeding; are a woman before menopause (unless you have been diagnosed with breast cancer or are taking Prolia for the treatment or prevention of osteoporosis related to the use of corticosteroid medicines); are currently taking denosumab under the brand name XGEVA®; do not have access to a healthcare professional or trained injector.


Warnings and precautions: Prolia contains the same medicine as another drug called XGEVA but at a different dose. If you are being treated with Prolia, you should not be taking XGEVA or vice versa. You should take calcium and vitamin D supplements as recommended by your healthcare professional. Tell your doctor and pharmacist about all the medicines you take, including prescription and

nonprescription drugs, vitamins and herbal supplements, and keep an up-to-date list of all of them. The needle cover on the single-use prefilled syringe contains dry natural rubber (latex), which should not be handled by persons allergic to it. Do not take Prolia if you are pregnant or could become pregnant as it may harm your unborn baby. Your healthcare professional should do a pregnancy test before you start treatment with Prolia. Use an effective birth control method during Prolia treatment and for at least 5 months after your last dose. If you become pregnant while on Prolia, stop taking it and tell your doctor right away.

Before you use Prolia: Talk to your doctor or pharmacist if you: have low blood calcium; cannot take daily calcium and vitamin D; have had parathyroid or thyroid surgery (glands located in your neck); have been told you have trouble absorbing minerals in your stomach or intestines (malabsorption syndrome); have kidney problems or are on kidney dialysis; have ever had an allergic reaction to Prolia; plan to have dental surgery or teeth removed; have a history of cancer; are pregnant or could become pregnant; are allergic to rubber or latex.

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Patient Information pad,
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