

Getting started on Prolia[®]




Pr **prolia**[®]
denosumab

Start and stay with the proVital® Support Program

To speak with the ProVital® Support Program, call 1-877-PRO-1002 (1-877-776-1002) toll-free from 8:00 a.m. to 8:00 p.m. EST, Monday to Friday, or visit the program website at www.prolia.ca. You will need the Prolia DIN to access the website. The Prolia **DIN** is **02343541**.



A Drug Identification Number (DIN) is an eight-digit number that uniquely identifies a drug in Canada. You will need the Prolia DIN to enter the Prolia.ca website. This can be found on the box of your Prolia.

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The information contained in this booklet is for your information only and is not intended to replace the medical advice of your doctor or healthcare professional. Speak with your doctor or healthcare professional if you have any questions about your medical condition or treatment with Prolia.

Getting started on Prolia

Understanding your treatment

This guide was developed to help you better understand your treatment and answer any questions you may have about Prolia, including how it works, how to take it, what you can expect and other steps you can take to manage bone health.

You'll also find information about the ProVital Support Program, your resource to help you stay on track with your Prolia treatment.

For more information on Prolia or ProVital, visit www.prolia.ca or call **1-877-PRO-1002** (1-877-776-1002).





What is Prolia?

Prolia is used to treat osteoporosis (thinning and weakening of bone) in women after menopause who have an increased risk for fractures or cannot use other osteoporosis medicines, or for whom other osteoporosis medicines did not work well.

Prolia is also used to increase bone mass in men with osteoporosis at high risk for fracture.

As with all prescription medications, it's important that you **take Prolia as directed by your doctor** – and that you continue to take it for as long as your doctor recommends.

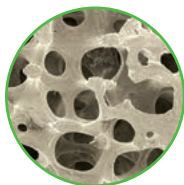
Getting started on Prolia

Why have I been prescribed Prolia?

Your doctor has prescribed Prolia for your osteoporosis.

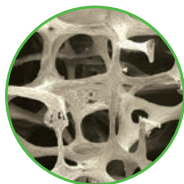
What is osteoporosis?

Bones are constantly changing.



Healthy bone

Normally, there is a balance between cells removing old bone and those creating new bone.



Osteoporotic bone

When you have osteoporosis, more bone is removed than is replaced resulting in bone loss. Your bones are thinner, weaker and more likely to break.

1 in 4 women and at least **1 in 8** men
over the age of 50 years have osteoporosis.

At least **1 in 3** women will experience an osteoporosis-related fracture during their lifetime.

Osteoporosis facts

- It is a bone disease **not** a normal part of aging.
- Called “the silent thief” because bone loss may occur without symptoms.
- First sign of osteoporosis is often a broken bone.
- A *fragility fracture* is a bone break caused by a minor fall (from a standing height or less), or from daily activities (lifting groceries, getting out of bed). A fragility fracture significantly increases the risk of future fractures.

How does Prolia work?

Prolia works differently than other osteoporosis medications. 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.

How do I take Prolia?

Prolia is administered as a single injection under the skin every 6 months. The injection can be in your upper arm, upper thigh or abdomen.

It can be given by a health professional or trained injector at any time of day, with or without food.



Use the reminder card in the carton to track your upcoming Prolia injection appointment.

Getting started on Prolia

How do I prepare for my next Prolia treatment?

- You will likely need to fill your Prolia prescription at a pharmacy. Plan to contact your pharmacy a few days before your appointment to order your Prolia.
- Store Prolia in your refrigerator in its original carton until your injection appointment – do not freeze.
- Once removed from the refrigerator, Prolia must be kept at room temperature (up to 25°C) in the original carton to protect it from light, and must be used within 30 days.
- Do not use Prolia after the expiry date on the carton and label.

Remember to schedule your Prolia injection appointment every 6 months from the date of your last injection. If you miss a dose, make sure you receive your missed dose as soon as possible.

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
- A 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
- Allergic reactions (e.g. rash, hives, or in rare cases, swelling of the face, lips, tongue, throat or trouble breathing)
- Rash that may occur on the skin or sores in the mouth (lichenoid drug eruption)
- Skin infection with 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:

Fever or chills
(infection)

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

Sore in mouth involving gums
or jaw bones (osteonecrosis of
the jaw)

Stop taking drug and call your
doctor or pharmacist.

Low blood calcium
symptoms (muscle
spasms, twitches,
cramps, numbness
or tingling in the
fingers, toes or
around the mouth)

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's important to contact your doctor or pharmacist if you're 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.

The ProVital Support Program –

helping you start and stay on track





The ProVital Support Program – helping you start and stay on track

What is the ProVital Support Program?

ProVital is a reminder and education program that 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
- Reminder calls one month before and after your appointment
- Newsletter series that is educational and keeps you on track with the Program



How do I enrol in the ProVital Support Program?



**Call 1-877-776-1002 (toll-free),
8:00 a.m. to 8:00 p.m. EST, Monday to Friday**



**Fill out and send the postage-paid enrolment card
in this pamphlet**



Visit Prolia.ca

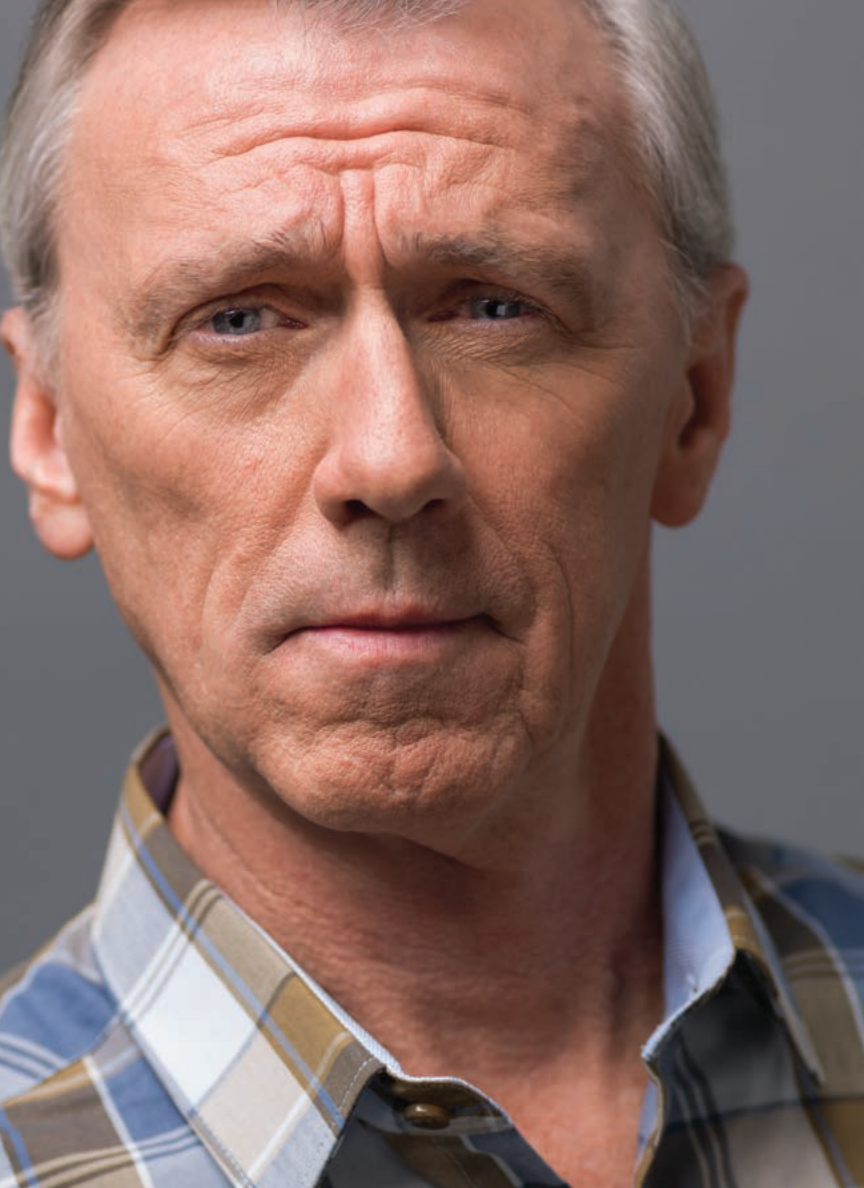


**Fax – Simply sign the ProVital fax enrolment form
in your doctor's office**



Lifestyle tips to manage your osteoporosis





Lifestyle tips to manage your osteoporosis

What else can I do for osteoporosis?

There's a lot you can do.

Start on Prolia –

and stay on it for as long as your doctor recommends

- Osteoporosis doesn't go away, so it's important to take Prolia exactly as directed by your doctor

Be nutrition-wise –

calcium and vitamin D are essential to bone health

- Eating foods that are rich in these nutrients and taking supplements as recommended by your doctor can be helpful in maintaining, and even improving your bone health

Keep moving –

strength exercises can be beneficial to your bones

- Exercise is beneficial at any point in life by helping to strengthen bones and muscles. Please consult with your doctor before you start any new exercise program

The more you know about your condition, the better equipped you'll be to manage your osteoporosis. Be proactive in managing your condition – from diagnosis through to starting and staying on the treatment your doctor has prescribed, and making healthy lifestyle choices.

How can I make sure I'm getting enough calcium and vitamin D?

Daily calcium and vitamin D requirements increase with age. Use the table below to determine how much of these essential nutrients you need.*

Recommended daily requirement*

Age	Calcium (mg)	Vitamin D (IU)
19-50 years	1000	400-1000
50+ years	1200	800-2000

IU=international units

* Total diet plus supplement. Healthy adults between 19 and 50 years of age require 400 to 1000 IU daily. Those over 50 years or younger adults at high risk (those with osteoporosis, multiple fractures or conditions affecting vitamin D absorption) should receive 800 to 2000 IU daily. Taking more than 2000 IU of vitamin D daily should be done only under medical supervision.



Lifestyle tips to manage your osteoporosis

How can I make sure I'm getting enough calcium?

Making sure you get enough calcium is an important step towards good bone health. By doing so, you'll maintain an adequate supply so that your body doesn't have to dip into the reserve of calcium in your bones.



It's strongly recommended that you get the calcium you need from your diet whenever possible.



If you can't get enough calcium from the foods you eat, you can also take a supplement.

What are some easy ways to work high-calcium foods or beverages into my diet?*

- Start the day with a cup of milk in your hot or cold cereal – just one cup of milk contains at least 300 mg of calcium[†]
- Adding a slice of cheese to a sandwich or having a canned salmon sandwich are both excellent lunchtime ideas that add another 200 to 245 mg of calcium
- For supper, a tofu stir-fry with a cup of green vegetables such as broccoli and kale can boost your calcium approximately 200 mg

* Approximate values.

† Calcium-enriched milk provides an additional 100 mg of calcium per serving.

For more information on calcium content in common foods, delicious calcium-rich recipes and more, sign up for the ProVital Support Program today!

How can I make sure I'm getting enough vitamin D?

Vitamin D helps your body absorb calcium from the foods you eat.

Your body naturally produces vitamin D when you're exposed to sunlight. However, during the winter months, most Canadians do not get enough sun exposure to produce adequate amounts of vitamin D. The best way to enhance your vitamin D intake is through dietary sources and supplements.

What are some easy ways to work high-vitamin D foods or beverages into my diet?

- Vitamin D fortified milk, yogurt and orange juice
- Several kinds of fish – such as salmon, sardines and swordfish – and some fish oils (halibut and cod liver oil)
- Whole eggs (vitamin D is found in the yolk)
- Ready-to-eat cereal (fortified with 10% of the daily value for vitamin D)



Lifestyle tips to manage your osteoporosis

How can I optimize my diet and nutrition?

In addition to getting enough calcium and vitamin D, here are a few more things to keep in mind when planning your meals:

Consume caffeine, alcohol and salt with moderation

- Coffee, tea and soft drinks contain caffeine which may decrease calcium absorption and contribute to bone loss – choose these drinks in moderation
- Avoid excessive alcohol intake – consume no more than two alcoholic drinks per day
- High-salt foods should be monitored – try to limit your sodium intake to no more than 2300 mg/day (about one teaspoon of salt)

Power up on protein

- Ask your doctor how much you need



Can physical activity help strengthen my bones?

Physical activity is important for people living with osteoporosis as it helps to build and maintain healthy bones.

A program that combines different forms of physical activity can provide the greatest benefit to your bones. Try a few of these to start – and be sure to ask your doctor for a full list of activities you should be doing.

Aerobic activity

These are exercises that get your heart rate up – you should feel like your heart is beating faster and you are breathing harder.

Strength and resistance exercises

Use weights, elastic exercise bands or even your own body weight to increase muscle and bone strength.

Balance and coordination

Activities like tai chi and swimming help improve your balance and coordination to decrease your risk of falling.

Fall prevention program

If you have a tendency to fall, ask your doctor about getting assessed for an individualized fall prevention program.

Lifestyle tips to manage your osteoporosis

Where can I find more information?

Prolia.ca is your online resource for more information on Prolia and postmenopausal osteoporosis. Visit www.prolia.ca today (DIN: 02343541).

Here are some additional online resources you might find helpful:

Osteoporosis Canada

www.osteoporosis.ca

Canadian Menopause Society

www.sigmamenopause.com

Canada's Physical Activity Guide for Older Adults

www.phac-aspc.gc.ca/hp-ps/hl-mvs/pa-ap/08paap-eng.php

Dietitians of Canada

www.dietitians.ca

Canadian Orthopaedic Foundation

www.canorth.org

National Osteoporosis Foundation (US)

www.nof.org

North American Menopause Society

www.menopause.org

Warnings and precautions not listed below are discussed on page 6 of this booklet under "Does Prolia cause any side effects?" For more information or to obtain a copy of the full Product Monograph, contact the ProVital Support Program 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.

Prolia may interfere with normal bone and tooth development in fetuses, nursing babies and children under 18 years of age. Do not take Prolia if you are pregnant or could become pregnant as Prolia may harm your unborn baby. Your healthcare provider should do a pregnancy test before you start Prolia treatment. You should use an effective birth control method during treatment and for at least 5 months after your last dose of Prolia. If you become pregnant while taking Prolia, stop taking Prolia and tell your doctor right away. Nursing mothers should not take Prolia. It may also interfere with breastfeeding.

Prolia may lower levels of calcium in the blood (reported in greater than or equal to 0.01%, less than 0.1% of patients). Low blood calcium should be treated before receiving Prolia. Symptoms of low blood calcium may include muscle spasms, twitches, cramps, numbness or tingling in hands, feet or around the mouth, and weakness (though some patients may not have any symptoms of low calcium). Tell your doctor if you have any of these symptoms. Tell your doctor right away if you have symptoms of infection, including: fever or chills, skin that looks red, swollen, hot or tender to touch, severe abdominal pain, frequent or urgent need to urinate or burning feeling when you urinate.

Tell your doctor if you have any of the following symptoms of skin problems that do not go away or get worse: redness; itching, rash; dry or leathery skin; open, crusted or peeling skin; blisters.

After you start Prolia: Take good care of your teeth and gums, and see your dentist regularly. If you have a history of dental problems (such as poorly fitting dentures or gum disease), see your dentist before starting Prolia. Tell your dentist that you are taking Prolia, especially if you are having dental work.

A dental condition called osteonecrosis of the jaw (which can cause tooth and jawbone loss) has been reported in patients treated with Prolia (reported in greater than or equal to 0.01%, less than 0.1% of patients). Tell your doctor and dentist immediately about any dental symptoms.

Some people have developed unusual fractures in their thigh bone (atypical femoral fractures, reported in greater than or equal to 0.01%, less than 0.1% of patients). Contact your doctor if you experience new or unusual pain in your hip, groin or thigh.

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.

Start and stay with the ProVital Support Program

The program helps you learn about osteoporosis and manage your Prolia® treatment

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
- Reminder calls one month before and after your appointment
- Newsletter series that is educational and keeps you on track with the Program

Get started and stay on track –
join the ProVital Support Program today

Simply fill out and
return this card today!




Pr **prolia**®
denosumab

To enrol in the ProVital® Support Program, simply fill out this card.

Please complete the following contact information.

Patient name: _____

Date of birth: (mm/dd/yyyy) _____ / _____ / _____

Address: _____

City: _____

Province: _____ Postal code: _____

Phone: _____

Message OK?: _____

Contact name (if other than patient name) and relationship:

Prescribing doctor's name: _____

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used with permission.



Authorization

We respect your right to privacy. McKesson Canada Corporation ("McKesson Canada") is the administrator of the ProVital Support Program ("Program"). The personal information you provide to McKesson Canada, including your personal health information such as name, contact information and prescription information, will be used to provide you with the Program's prescription fulfilment and adherence assistance services, including forwarding product or prescriptions to your healthcare professionals, providing prescription reminders, answering product inquiries and/or supplying educational materials, as well as to allow McKesson Canada to conduct confidential surveys about the Program.

To facilitate delivery of these Program services, McKesson Canada may disclose your personal information on a confidential basis to: (i) Amgen Canada Inc. ("Amgen"), the manufacturer of Prolia (denosumab); and/or (ii) authorized agents and service providers. Please note that these service providers (e.g. information technology providers), McKesson Canada and Amgen may store or process your data outside of Canada for maintenance purposes and may therefore be subject to additional local legislation. Other jurisdictions may have laws and regulations that require the disclosure of personal information to governmental authorities under different circumstances than would Canada. In addition, your personal information may be disclosed to Amgen or other third parties when permitted or required by applicable laws, court orders or government regulations (collectively, "Applicable Laws").

McKesson Canada and Amgen will retain your personal information only for the time required to fulfil the purposes for which it was collected and in order to comply with Applicable Laws. McKesson Canada and Amgen use industry standard safeguards to protect the security of the personal information that we collect. You may contact McKesson Canada at 1-877-776-1002 at any time to update or access your personal information, modify or withdraw your consent (in part or in full), express a privacy-related concern, or inquire about privacy practices for the Program. Please note that if you modify or withdraw your consent, McKesson Canada's ability to deliver the Program services to you may be limited.

Consent

By signing this form, I acknowledge that I have read and understand the above information and consent to the collection, use and disclosure of my personal information, including personal health information, by McKesson Canada, Amgen and their authorized agents and service providers, as explained above. I further consent to being contacted from time to time by McKesson Canada, Amgen or their authorized agents and service providers for the above-noted purposes.

Please sign the space provided below – then seal and mail.

Name of patient: _____

Name of caregiver: _____

Relationship to patient: _____

Signature of patient or caregiver: _____

Date: _____



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PROVITAL PROGRAM

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Start and stay
with the **proVital**[®]
Support Program

**Join the ProVital Support
Program today**

1-877-776-1002 (toll-free) • www.prolia.ca (DIN: 02343541)

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