# Prolia

**Pronunciation:** *PRO-lee-a*
**Generic name:** denosumab
**Dosage form:** injection for subcutaneous use
**Drug class:** Miscellaneous bone resorption inhibitors

Medically reviewed by Carmen Pope, BPharm. Last updated on Apr 1, 2025.



## What is Prolia?

Prolia (denosumab) is an injection that is administered subcutaneously (under the skin) once every 6 months by a healthcare provider to:

- Treat osteoporosis in postmenopausal women at high risk for fracture
- Increase bone mass in men with osteoporosis at high risk for fracture
- Treat glucocorticoid-induced osteoporosis in men and women at high risk for fracture
- Increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer
- Increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

Bone is always breaking down and reforming. Everyone has osteoclasts that dissolve old and damaged bone and osteoblasts that form new bones and add growth to existing bone tissue. Prolia works by stopping the formation of osteoclasts before they can reach and damage the bone. It binds to RANKL, which is a protein on the membrane of osteoclasts that is essential for their formation, function, and survival. This inhibits osteoclast formation, which decreases bone resorption and increases bone mass and strength in both cortical (hard bone) and trabecular (spongy bone) bone. Prolia is a monoclonal antibody that targets and inhibits RANK ligand (RANKL).

Prolia was FDA-approved on June 1, 2010. There are currently 3 biosimilars to Prolia:

- Jubbonti (denosumab-bbdz) made by Sandoz Inc. (FDA approval March 5, 2024).
- Ospomyv (denosumab-dssb) made by Samsung Bioepis (FDA approval February 16, 2025)
- Stoboclo (denosumab-bmwo) made by Celltrion (FDA approval February 28, 2025)
- Conexxence (denosumab-bnht) made by Fresenius Kabi (FDA approval March 25, 2025).

## Xgeva vs Prolia

Xgeva is another brand of denosumab that is used to prevent bone fractures, other skeletal conditions, and high blood calcium levels in certain people with cancer.

- Xgeva and Prolia have different dosages and uses and are not interchangeable (see Xgeva vs Prolia: How do they compare? for more information).

## Warnings

Prolia carries a boxed warning for life-threatening severe hypocalcemia (very low calcium levels); the risk is higher in patients with advanced chronic kidney disease (CKD), particularly those on dialysis. The risk increases even more in those with CKD who also have a condition known as mineral and bone disorder (CKD-MBD). Your healthcare provider will evaluate you for hypocalcemia and CKD-MBD before starting treatment and monitor you throughout. Pre-existing low calcium levels should be corrected before starting treatment.

If you receive Prolia, you should not receive Xgeva, Wyost, or Jubbonti. Prolia contains the same medicine (denosumab).

Serious and life-threatening hypersensitivity reactions have occurred with Prolia, including anaphylaxis. Seek emergency help or tell your doctor immediately if you experience shortness of breath, throat tightness, swelling of the airways and throat, itching, low blood pressure, or hives.

Osteonecrosis of the jaw has been reported with Prolia. A routine oral exam should be performed before Prolia treatment and preventive dentistry undertaken if necessary, especially for those with risk factors such as prior tooth extraction, dental implants, oral surgery, cancer,  or poor oral hygiene. Good oral hygiene practices should be maintained during treatment with Prolia.

Atypical low energy or low trauma femoral fractures have been reported with Prolia. Contact your doctor immediately if you develop thigh or groin pain. Multiple vertebral fractures have been reported following Prolia discontinuation. Your healthcare provider should consider transitioning you to another antiresorptive agent.

Serious infections including skin infections may occur, including those leading to hospitalization. Seek emergency help or tell your healthcare provider immediately if you develop any signs or symptoms of an infection, including cellulitis (symptoms include a red, swollen, and painful area of skin that is warm and tender to the touch. Some people may also develop fever and chills).

Other severe side effects including severe skin rashes and eczema, bone over-suppression, or severe bone, joint, or muscle pain may occur. Tell your healthcare provider immediately.

## Before taking

Tell your doctor about all of your medical conditions, including if you:

- are allergic to denosumab or latex
- are taking a medicine called Xgeva (denosumab). Xgeva contains the same medicine as Prolia
- have low blood calcium
- cannot take daily calcium and vitamin D

- had parathyroid or thyroid surgery (glands located in your neck) or intestinal surgery
- have been told you have trouble absorbing minerals in your stomach or intestines (malabsorption syndrome)
- have kidney problems or are on kidney dialysis
- have a weak immune system
- are taking medicine that can lower your blood calcium levels
- plan to have dental surgery or teeth removed
- are pregnant or plan to become pregnant. Prolia may harm your unborn baby
- are breastfeeding or plan to breastfeed.

### Pregnancy

For females who can become pregnant, your healthcare provider should do a pregnancy test before you start treatment with Prolia. You should use an effective method of birth control (contraception) during treatment with Prolia and for at least 5 months after your last dose. Tell your doctor right away if you inadvertently become pregnant.

### Breastfeeding

It is not known if Prolia passes into your breast milk. You and your doctor should decide if you will take Prolia or breastfeed. You should not do both.

Prolia pregnancy and breastfeeding warnings (more detail)

## How is Prolia administered?

Prolia is an injection that will be given to you by a healthcare professional. Prolia is injected under your skin (subcutaneously).

- You will receive Prolia 1 time every 6 months.
- You should take calcium and vitamin D as your doctor tells you to while you receive Prolia.
- Take good care of your teeth and gums while you receive Prolia. Brush and floss your teeth regularly. If you need to have any dental work (especially surgery), tell the dentist ahead of time that you are using Prolia. You may need to stop using the medicine for a short time.

Talk with your doctor before starting Prolia treatment. After your treatment with Prolia is stopped, or if you skip or delay taking a dose, your risk of breaking bones, including bones in your spine, is increased. Your risk of having more than 1 broken bone in your spine is increased if you have already had a broken bone in your spine. Do not stop, skip, or delay taking Prolia without first talking with your doctor. If your Prolia treatment is stopped, talk to your doctor about other medicines that you can take.

- Your risk of bone fractures can increase when you stop, skip, or delay using Prolia. Do not stop using this medicine without first talking to your doctor.

Detailed Prolia dosage information

## What happens if I miss a dose?

Call your doctor for instructions if you miss a dose or miss an appointment for your Prolia injection. You should receive your missed injection as soon as possible.

## What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

## What are the side effects of Prolia?

Serious allergic reactions have happened in people who take Prolia. Call your doctor or go to your nearest emergency room right away if you have any symptoms of a serious allergic reaction such as low blood pressure (hypotension), trouble breathing, throat tightness, swelling of your face, lips, or tongue, rash, itching, or hives.

Prolia can cause serious side effects including:

- Increased risk of severe low calcium levels in your blood (hypocalcemia). Prolia may lower the calcium levels in your blood. If you have low blood calcium before you start receiving Prolia, it may get worse during treatment. Your low blood calcium must be treated before you receive Prolia. Talk to your doctor before starting Prolia. Your doctor may prescribe calcium and vitamin D to help prevent low calcium levels in your blood while you take Prolia. Take calcium and vitamin D as your doctor tells you to. Most people with low blood calcium levels do not have symptoms, but some people may have symptoms. Call your doctor right away if you have symptoms of low blood calcium such as spasms, twitches, or cramps in your muscles, or numbness or tingling in your fingers, toes, or around your mouth
- Severe jaw bone problems (osteonecrosis). Your doctor should examine your mouth before you start Prolia. Your doctor may tell you to see your dentist before you start Prolia. You need to practice good mouth care during treatment with Prolia.
- Unusual thigh bone fractures. Symptoms of a fracture include new or unusual pain in your hip, groin, or thigh
- Increased risk of broken bones, including broken bones in the spine, after stopping, skipping, or delaying Prolia
- Serious infections in your skin, lower stomach area (abdomen), bladder, ear, or heart. You may need to go to the hospital for treatment if you develop an infection. Call your doctor right away if you develop:
    - fever or chills
    - skin that looks red or swollen and is hot or tender to touch
    - shortness of breath, cough that will not go away
    - severe abdominal pain
    - frequent or urgent need to urinate or a burning feeling when you urinat
- Skin problems such as inflammation of your skin (dermatitis), rash, and eczema. Call your doctor if you have any of the following symptoms that do not go away or get worse: redness, itching, small bumps or patches (rash), your skin is dry or feels like leather, blisters that ooze or become crusty, skin peeling
- Bone, joint, or muscle pain.

Common Prolia side effects may include:

- bladder infection (painful or difficult urination)
- lung infection (cough, shortness of breath)

- headache
- back pain, muscle or joint pain
- increased blood pressure
- cold symptoms such as stuffy nose, sneezing, sore throat
- high cholesterol or
- pain in your arms or legs.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Prolia side effects (more detail)

## Related/similar drugs

### Fosamax

Fosamax (alendronate) is used to treat or prevent postmenopausal osteoporosis and steroid-induced ...

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Xgeva (denosumab) prevents bone fractures and other skeletal conditions in people with multiple ...

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## Tymlos

Tymlos (abaloparatide) is used to treat osteoporosis in men and postmenopausal women who have a ...

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5.1 / 10

108 Reviews

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## What should I avoid while receiving Prolia?

Follow your doctor's instructions about any restrictions on food, beverages, or activity.

## What other drugs will affect Prolia?

Other drugs may interact with denosumab, including prescription and over-the-counter medicines, vitamins, and herbal products. Tell your doctor about all other medicines you use.

- The use of calcimimetic drugs, such as cinacalcet, may worsen hypocalcemia risk.
- The use of other drugs associated with ONJ, such as bisphosphonates, may increase the risk of developing ONJ.

See the prescribing information for a full list of interactions.

Prolia drug interactions (more detail)

### Does Prolia interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.

Prolia

+

Enter a drug name Add

## Storage

Keep Prolia in a refrigerator at 36°F to 46°F (2°C to 8°C) in the original carton. Do not freeze.

Prolia may be kept out of the refrigerator for up to 14 days at room temperature [up to 77°F (25°C)] in the original carton to protect from light. Do not keep Prolia at temperatures above 77°F (25°C). Warm temperatures will affect how Prolia works.

Do not shake.

Keep Prolia and all medicines out of the reach of children.

## Ingredients

Active: denosumab

Inactive: sorbitol, acetate, polysorbate 20, Water for Injection (USP), and sodium hydroxide

## Manufacturer

Amgen.

# Prolia Biosimilars

Biosimilar and interchangeable products are biological products that are highly similar to and have no clinically meaningful differences from the reference product.

## Reference products

These are biological products that have already been approved by the FDA, against which biosimilar products are compared. There are 2 for Prolia.

**Prolia (denosumab) - Amgen Inc.**

| Formulation type | Strength |
|---|---|
| Pre-Filled Syringe | 60 mg/mL |
| Single-Dose Vial | 60 mg/mL **Discontinued** |

Xgeva (denosumab) - Amgen Inc.

## Prolia, Xgeva interchangeable products

Interchangeable biosimilar products can be dispensed by a pharmacist without the intervention of the prescriber of the reference product.

Pharmacy laws for biosimilar prescribing may vary by state.

Jubbonti (denosumab-bbdz) - Sandoz Inc.

Wyost (denosumab-bbdz) - Sandoz Inc.

# Popular FAQ

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How do you give a Prolia injection?

Does Prolia cause weight gain?

Does Prolia increase bone density?

Xgeva vs Prolia. How do they compare?

Can you drink alcohol while taking Prolia?

## More FAQ

- How many years should you take Prolia?

View more FAQ…


**References**

1. Prolia Package Insert


# More about Prolia (denosumab)

- Check interactions
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- Breastfeeding
- En español

## Patient resources

### Other brands

Xgeva, Jubbonti, Wyost

## Professional resources

- Prolia prescribing information
- Denosumab (AHFS Monograph)

### Other brands

Xgeva

## Related treatment guides

- Osteoporosis

# Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Medical Disclaimer

**DRUG STATUS**

**Availability**
**Rx** Prescription only

**Pregnancy & Lactation**
Risk data available

**CSA Schedule***
**N/A** Not a controlled drug

**Approval History**
**10+ years** FDA approved 2010

### User Reviews & Ratings

2.9 / 10

374 Reviews

### Related News

FDA Approves Bomyntra (denosumab-bnht), a Biosimilar to Xgeva

FDA Approves Conexxence (denosumab-bnht), a Biosimilar to Prolia

FDA Approves Osenvelt (denosumab-bmwo), a Biosimilar to Xgeva

### Images

Prolia 60 mg/1 mL in a single-dose prefilled syringe








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