

Injection instructions

What is Prolia®?

Prolia is used for the treatment of 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.

How to take Prolia

Prolia is administered as a single injection under the skin (subcutaneous) every 6 months. The injection can be in your upper arm, upper thigh, or abdomen. It can be given any time with or without food by a healthcare professional, by a trained injector, or a patient may self-inject if a healthcare professional determines that it is appropriate.

Your prefilled syringe may be left outside the refrigerator to reach room temperature (up to 25°C) before injection. This will make the injection more comfortable. See instructions for injection.

Keep all medicines, including Prolia, away from children.

Do not share a Prolia product with others, even if they have a similar disease.

Usual dose

The usual dose of Prolia is 60 mg administered once every 6 months. You should also take supplements of calcium and vitamin D.

Missed dose

If you miss a dose you should receive your next dose as soon as convenient. Schedule your next dose 6 months from the date of your last injection.

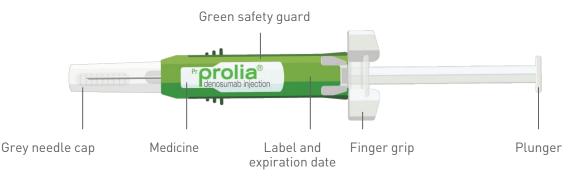
Overdose

If you think you have taken too much Prolia, contact a healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Before you inject

Important: The Prolia single-use prefilled syringe has a green safety guard that should be manually extended to cover the needle **after** the injection is given.

Do not slide the green safety guard forward over the needle **before** administering the injection – it will lock in place and prevent injection. Use another syringe that has not been activated and is ready to use.



The grey needle cap on the single-use prefilled syringe contains dry natural rubber (a derivative of latex), which should not be handled by persons sensitive to latex.

Do NOT remove the grey needle cap from the syringe until you are ready to inject.

Ask your healthcare provider if you have any questions on the use of Prolia. You may also refer to the Patient Medication Information leaflet that comes with your Prolia medication.

Step 1 – Prepare

A

Remove the prefilled syringe carton from the refrigerator.

Remove the syringe tray from the carton. On a clean, well-lit surface, place the syringe tray at room temperature for 15-30 minutes before you give an injection.

- Do NOT use the prefilled syringe if the carton is open or damaged.
- Do NOT try to warm the prefilled syringe by using a heat source such as hot water or microwave.



- Do NOT leave the prefilled syringe in direct sunlight.
- Do NOT shake the prefilled syringe.

Open the tray by peeling away the cover. Grab the green safety guard to remove the prefilled syringe from the tray.

For safety reasons: Do NOT grab the plunger rod or the grey needle cap.

Inspect the medicine and prefilled syringe.

Always hold the syringe by the syringe barrel. Make sure the medicine in the prefilled syringe is clear and colourless to pale yellow.

Do NOT use the prefilled syringe if:

- The medicine is cloudy or discoloured.
- Any part appears cracked or broken.
- It has been dropped. Part of the syringe may be broken even if you cannot see the break. Use a new syringe.
- The grey needle cap is missing or not securely attached.
- The expiration date printed on the label has passed.

In all cases, use a new prefilled syringe and call your healthcare professional or Amgen Medical Information at 1-866-502-6436.

С

B

Gather all materials needed for the injection.

Wash your hands thoroughly with soap and water.

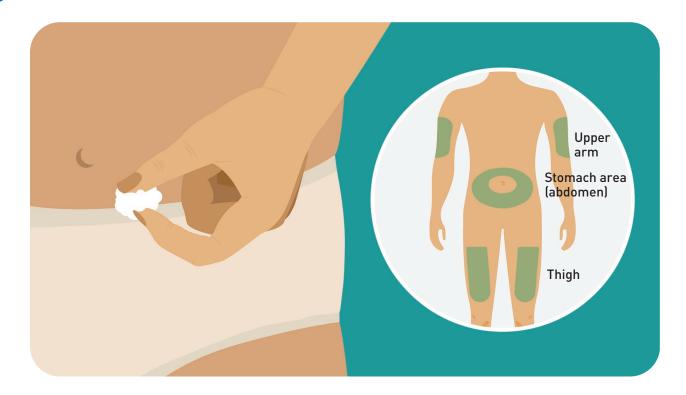
On a clean, well-lit work surface, place the:

- Prefilled syringe
- Alcohol wipe
- Cotton ball or gauze pad
- Adhesive bandage
- Sharps disposal container

Step 2 – Get ready

D

Prepare and clean the injection site.



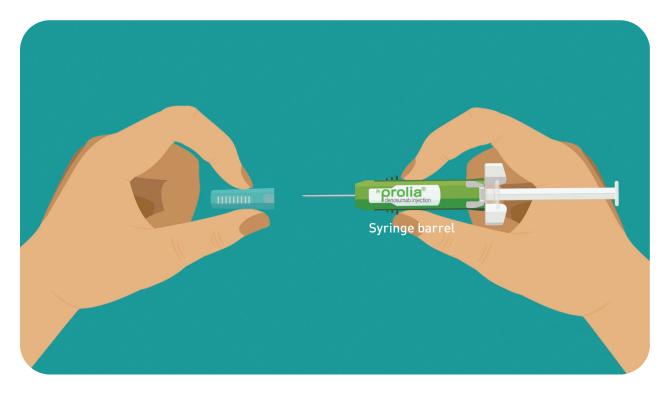
You can use:

- Upper thigh
- Stomach area (abdomen), except for a 5-cm (2-inch) area right around the navel (belly button)
- Outer area of upper arm (only if someone else is giving you the injection)

Clean the injection site with an alcohol wipe. Let the skin dry.

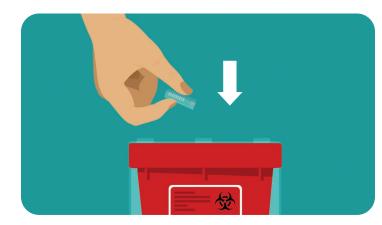
- Do NOT touch this area again before injecting.
- Do NOT inject into areas where the skin is tender, bruised, red or hard. Avoid injecting into areas with scars or stretch marks.

Hold the prefilled syringe by the syringe barrel. Carefully pull the grey needle cap straight off and away from the body.



- Do NOT remove the grey needle cap from the prefilled syringe until you are ready to inject.
- Do NOT twist or bend the grey needle cap.
- Do NOT hold the prefilled syringe by the plunger rod.
- Do NOT put the grey needle cap back onto the prefilled syringe.

Important: Throw the grey needle cap into the sharps disposal container.

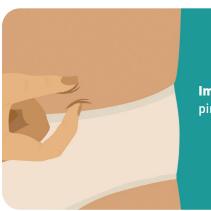


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Step 3 – Subcutaneous (under the skin) injection



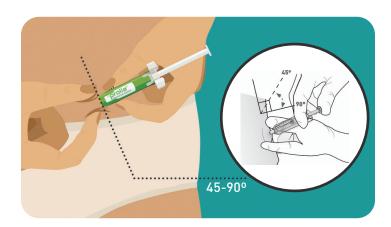
Pinch the injection site to create a firm surface.



Important: Keep skin pinched while injecting.



Hold the pinch. Insert the needle into the skin at 45 to 90 degrees.





Using slow and constant pressure, push the plunger rod until it reaches the bottom.

• Do NOT pull back the plunger rod while the needle is inserted.



When done, gently pull the syringe off of the skin.

Important: When you remove the syringe, if it looks like the medicine is still in the syringe barrel, this means you have not received a full dose. Call your healthcare professional right away.

Step 4: Finish



Before you finish!

For your safety, pull the green safety guard until it clicks and covers the needle.

Once extended, the green safety guard will lock into position and will not slide back over the needle.

Keep your hands away from the needle at all times.



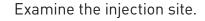


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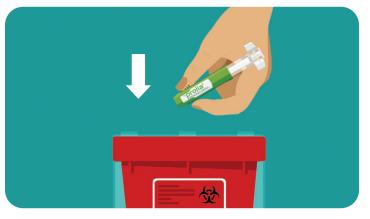
Discard (throw away) the used prefilled syringe.

- Put the used prefilled syringe in a sharps disposal container right away after use. Do NOT throw away (dispose of) the syringe in the household trash.
- If you do not have a sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
 - upright and stable during use
 - leak-resistant, and
 - properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be local laws about how you should throw away used needles and syringes.
- Do NOT reuse the prefilled syringe.
- Do NOT recycle the prefilled syringe or sharps disposal container or throw them into household trash.

Important: Always keep the sharps disposal container out of the reach of children.



If there is blood, press a cotton ball or gauze pad on the injection site. Do NOT rub the injection site. Apply an adhesive bandage if needed.





Questions?

To speak with the ProVital[®] Patient 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**.

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