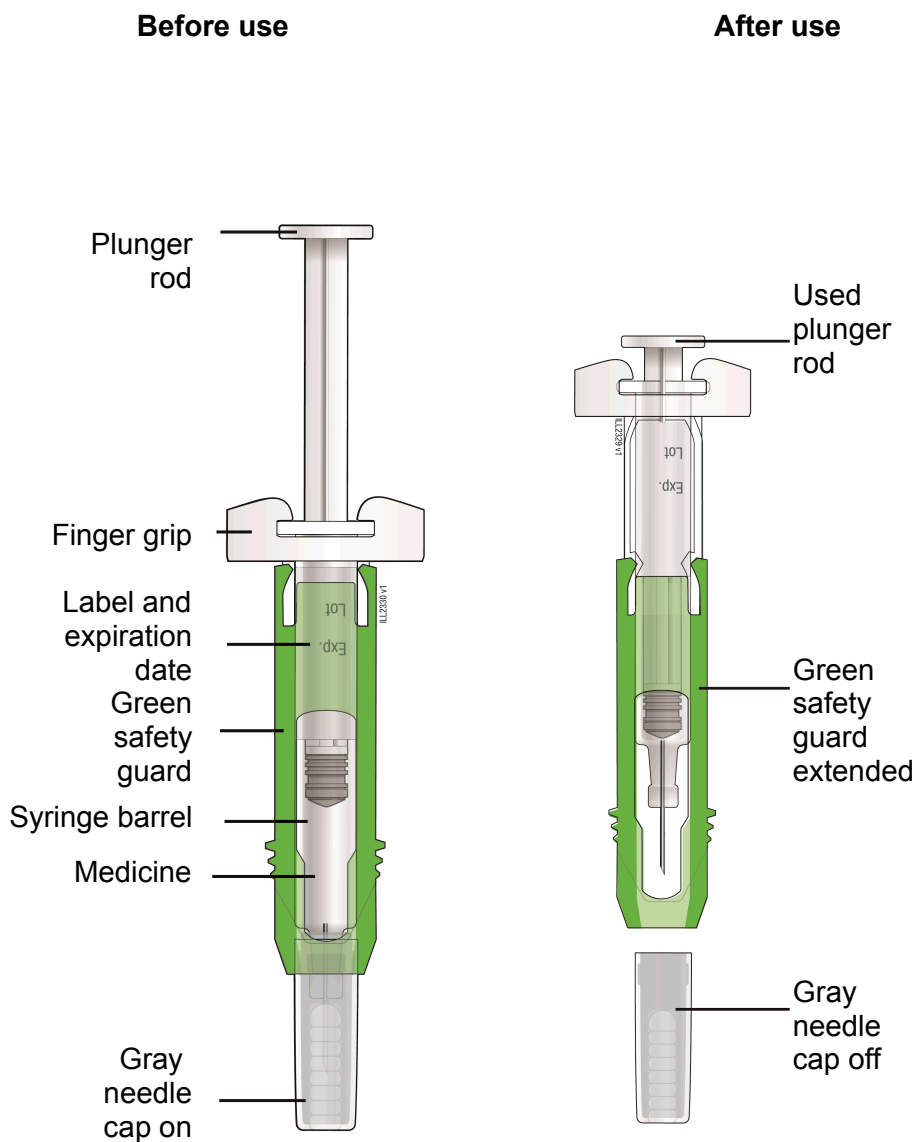


**Temporary Self-Administration Instructions for Use**  
**Prolia (PRÓ-lee-a)**  
**(denosumab)**  
**Injection, for subcutaneous use**  
**Single-Dose Prefilled Syringe**

Amgen is providing these Temporary Self-Administration Instructions for Use only during the COVID-19 public health emergency declared by the Secretary of Health and Human Services on January 31, 2020. They should be discarded following the public health emergency.

**Guide to parts**



**Important:** The needle is covered by the gray needle cap before use.

## Important

Read this Temporary Self-Administration Instructions for Use prior to self-administration of Prolia.

**Before you use a Prolia prefilled syringe, read this important information.**

### Storing the prefilled syringe

- Store Prolia in the refrigerator between 36°F to 46°F (2°C to 8°C).
- **Do not** freeze.
- Keep the prefilled syringe in the original carton to protect from light or physical damage.
- Take the prefilled syringe out of the refrigerator 15 to 30 minutes before use and allow it to reach room temperature before preparing an injection.
- **Throw away (dispose of) any Prolia that has been left at room temperature, 68°F to 77°F (20°C to 25°C), for more than 14 days.**
- Keep the Prolia prefilled syringe and all medicines out of the reach of children.

### Using the prefilled syringe

- **It is important that you do not try to give the injection unless you or your caregiver has received guidance from your healthcare provider.**
- Make sure the name Prolia appears on the carton and prefilled syringe label.
- Check the carton and prefilled syringe label to make sure the dose strength is 60 mg.
- **Do not** use a prefilled syringe after the expiration date on the label.
- **Do not** shake the prefilled syringe.
- **Do not** remove the gray needle cap from the prefilled syringe until you are ready to inject.
- **Do not** use the prefilled syringe if the carton is open or damaged.
- **Do not** use a prefilled syringe if it has been dropped on a hard surface. The prefilled syringe may be broken even if you cannot see the break. Use a new prefilled syringe.
- **Do not** slide the green safety guard over the needle before you give the injection. This will “activate” or lock the green safety guard. Use another prefilled syringe that has not been activated and is ready to use.
- **The gray needle cap on the prefilled syringe contains dry natural rubber (made from latex). Tell your healthcare provider if you are allergic to latex. You should not give Prolia if you have latex allergies.**

Call your healthcare provider or Amgen Medical Information at 1-800-77-AMGEN (1-800-772-6436) if you have any questions.

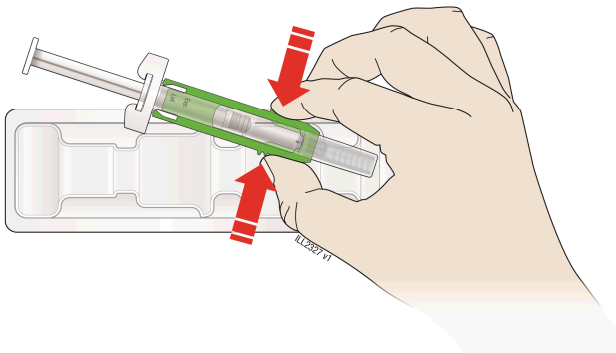
## Step 1: Prepare

**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 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.

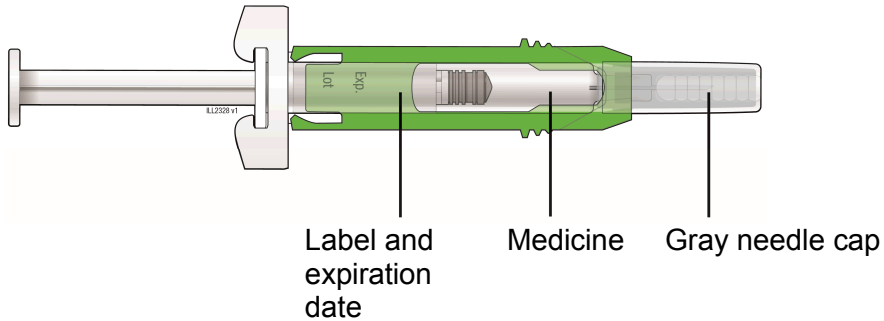


**Grab Green Safety Guard**

For safety reasons:

- **Do not** grab the plunger rod.
- **Do not** grab the gray needle cap.

**B** Inspect the medicine and prefilled syringe.



**Make sure the medicine in the prefilled syringe is clear and colorless to pale yellow.**

- **Do not** use the prefilled syringe if:
  - The medicine is cloudy or discolored or contains particles.
  - Any part appears cracked or broken.
  - The prefilled syringe has been dropped.
  - The gray 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 provider or Amgen Medical Information at 1-800-77-AMGEN (1-800-772-6436).

**C** Gather all materials needed for the injection.

Wash your hands thoroughly with soap and water.

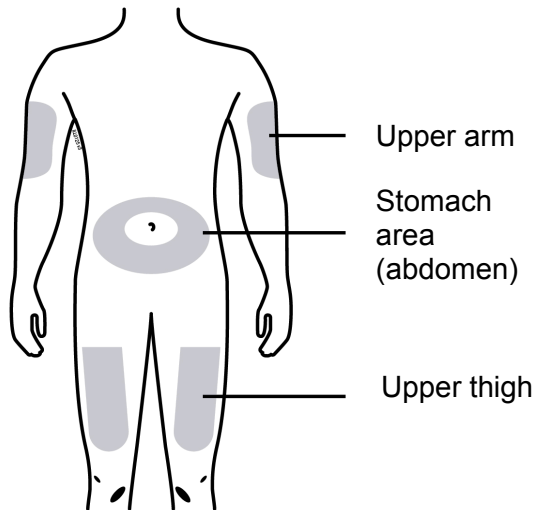
On a clean, well-lit work surface, place the:

- Prefilled syringe
- Alcohol wipe
- Cotton ball or gauze pad
- Adhesive bandage
- FDA cleared sharps disposal container



## Step 2: Get ready

D Prepare and clean the injection site(s).



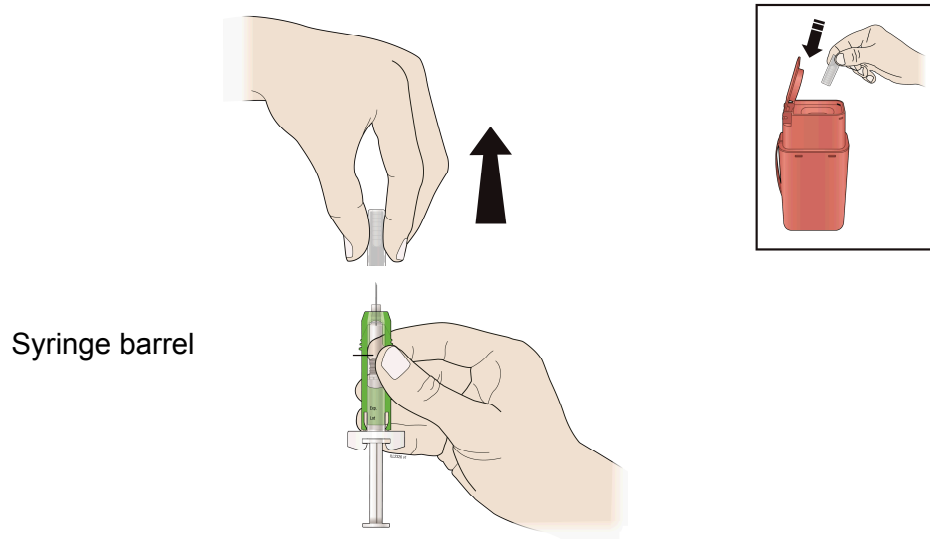
### You can use:

- Upper thigh
- Stomach area (abdomen), except for a 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.

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

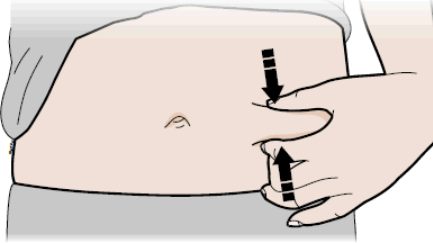


- **Do not** remove the gray needle cap from the prefilled syringe until you are ready to inject.
- **Do not** twist or bend the gray needle cap.
- **Do not** hold the prefilled syringe by the plunger rod.
- **Do not** put the gray needle cap back onto the prefilled syringe.

**Important:** Throw the gray needle cap into the FDA-cleared sharps disposal container.

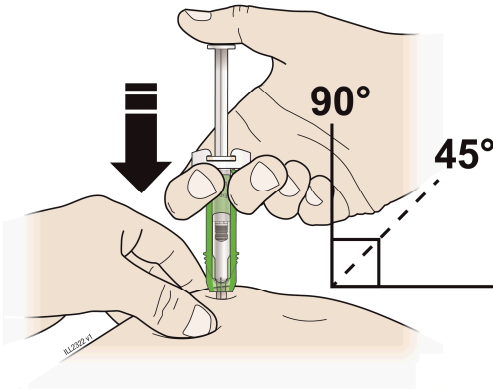
### Step 3: Subcutaneous (under the skin) injection

F Pinch the injection site to create a firm surface.



**Important:** Keep skin pinched while injecting.

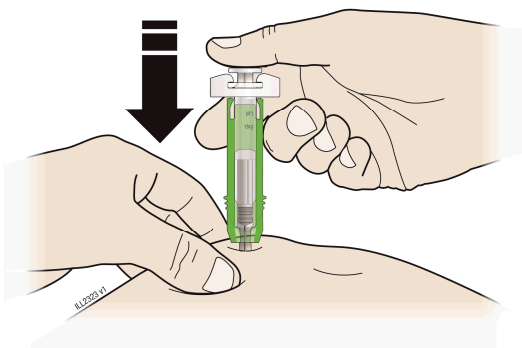
G Hold the pinch. Insert the needle into the skin at 45 to 90 degrees.



H 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.



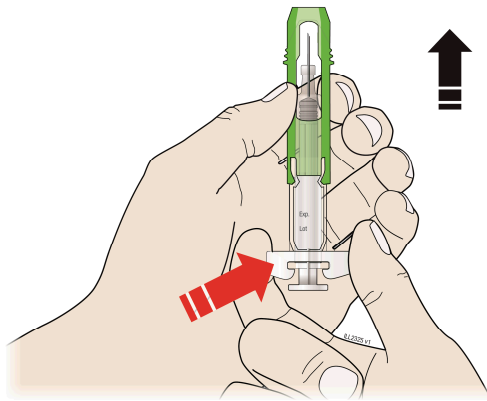
**Important:** When you remove the syringe, if it looks like the medicine is still in the syringe barrel, **this means you have not received a full dose. Call your healthcare provider right away.**

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**Step 4: Finish**



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



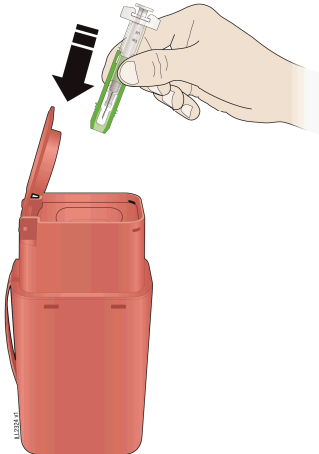
**GRAB  
HERE**

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.



**J** Discard (throw away) the used prefilled syringe.



- Put the used prefilled syringe in a FDA-cleared 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 FDA-cleared 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 state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>
- **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.

**K** Examine the injection site.

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.



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Patent: <http://pat.amgen.com/prolia/>

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