

**Instructions for Use
ZARXIO® (zar-zee-oh)
(filgrastim-sndz)
injection**

Important:

- **Do not inject yourself or someone else until you have been shown how to inject ZARXIO.** Your healthcare provider or nurse will show you how to prepare and inject ZARXIO properly using the ZARXIO prefilled syringe with UltraSafe Passive® Needle Guard. Talk to your healthcare provider or nurse if you have any questions.
- You should not inject a dose of ZARXIO less than 0.3 mL (180 mcg) from a ZARXIO prefilled syringe. A dose less than 0.3 mL cannot be accurately measured using the ZARXIO prefilled syringe.
- **Do not use** the ZARXIO prefilled syringe if either the seal on the outer pack or the seal of the blister are broken.
- Keep the ZARXIO prefilled syringe in the sealed pack until you are ready to use it.
- **The needle cap on the prefilled syringe contains natural rubber (derived from latex). Do not handle the prefilled syringe if you are allergic to latex.**
- The prefilled syringe has a needle guard that will be activated to cover the needle after the injection is given. The needle guard will help prevent needle stick injuries to anyone who handles the prefilled syringe.
- Avoid touching the syringe needle guard wings before use. Touching them may cause the syringe needle guard to be activated too early.
- Do not remove the needle cap until just before you give the injection.
- Throw away (dispose of) the used ZARXIO prefilled syringe right away after use. **Do not re-use a ZARXIO prefilled syringe.** See “How should I dispose of used ZARXIO prefilled syringes?” at the end of this Instructions for Use.
- Do not use if the syringe has been dropped onto a hard surface or dropped after removing the needle cap.

How should I store ZARXIO?

- Store ZARXIO in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Protect from freezing ZARXIO. If frozen, thaw in the refrigerator before use. Throw away (dispose of) if it has been frozen more than 1 time.
- Store ZARXIO in the original pack to protect it from light.
- Avoid shaking ZARXIO.
- Take ZARXIO out of the refrigerator 30 minutes before use and allow it to reach room temperature before preparing an injection.
- ZARXIO may be allowed to reach room temperature for up to 4 days. **Throw away (dispose of) any ZARXIO that has been left at room temperature for longer than 4 days.**
- After you inject your dose, throw away (dispose of) any unused ZARXIO left in the prefilled syringe. Do not save unused ZARXIO in the prefilled syringe for later use.

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

About the ZARXIO prefilled syringe:

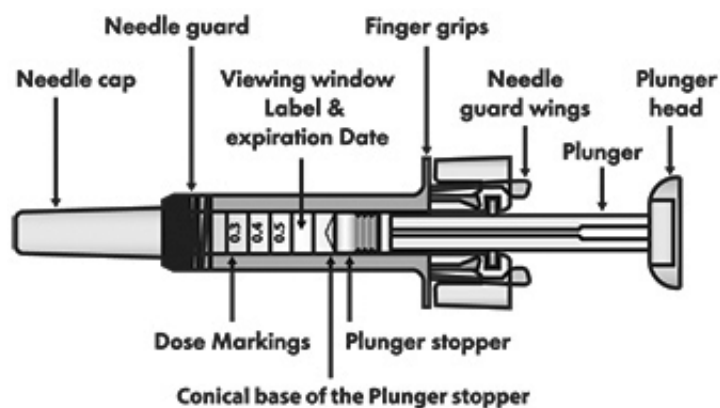
- ZARXIO prefilled syringes come in two strengths. Depending on your prescription, you will receive ZARXIO prefilled syringes that contain 300 mcg/0.5 mL or 480 mcg/0.8 mL of medicine. Your

healthcare provider will determine the dose in milliliters (mL) that you will need to give based on your body weight.

- When you receive your ZARXIO prefilled syringes, always check to see that the:
 - name ZARXIO appears on the pack and prefilled syringe label.
 - expiration date on the prefilled syringe label has not passed. **You should not use a prefilled syringe after the date on the label.**
 - strength of ZARXIO (number of micrograms on the pack containing the prefilled syringe) is the same as what your healthcare provider prescribed.

ZARXIO prefilled syringe parts (see Figure A). ZARXIO 300 mcg /0.5 mL prefilled syringe is shown as an example.

Figure A



What you need for your injection:

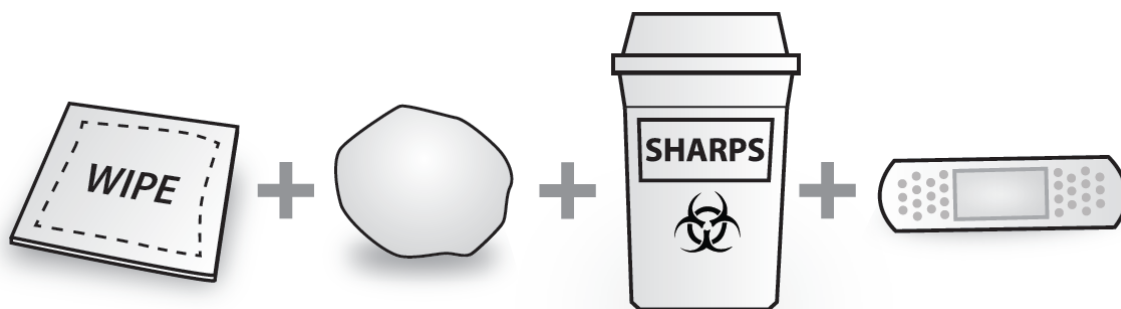
Included in the pack:

- A new ZARXIO prefilled syringe

Not included in the pack (**see Figure B**):

- 1 Alcohol wipe
- 1 Cotton ball or gauze
- Sharps disposal container
- 1 Adhesive bandage

Figure B



See “**How should I dispose of used ZARXIO prefilled syringes?**” at the end of this Instructions for Use.

Preparing the ZARXIO prefilled syringe

- Step 1. Find a clean, well-lit, flat work surface.
- Step 2. Take the pack containing the ZARXIO prefilled syringe out of the refrigerator and leave it **unopened on your work surface** for about 30 minutes so that it reaches room temperature.
- Step 3. Wash your hands well with soap and water.
- Step 4. Remove the ZARXIO prefilled syringe from the outer pack and take it out of the blister.
- Step 5. Check the expiration date. Do not use the ZARXIO prefilled syringe if the expiration date has passed.
- Step 6. Look through the viewing window on the ZARXIO prefilled syringe. The liquid inside should be clear. The color may be colorless to slightly yellow. You may see a small air bubble in the liquid. This is normal. **Do not use** the prefilled syringe if the liquid contains visible particles, or if the liquid is cloudy or discolored. Return the ZARXIO prefilled syringe and the package it came in to your pharmacy.
- Step 7. Do not use a ZARXIO prefilled syringe if it is broken. Return the broken prefilled syringe and the package it came in to your pharmacy.
- Step 8. Check to make sure that the plastic transparent needle guard is covering the barrel of the glass syringe. If the transparent needle guard is covering the needle cap (**see Figure C**) the needle guard has already been activated. **Do not use the prefilled syringe.**

Get another prefilled syringe that has not been activated and is ready to use (**see Figure D**).

Figure C shows a needle guard that has already been activated. **Do not use a ZARXIO prefilled syringe that has been activated.**

Figure C Do Not Use

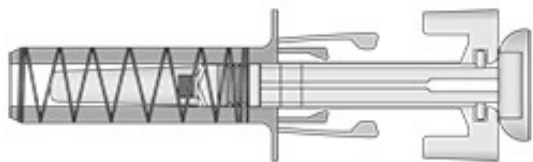
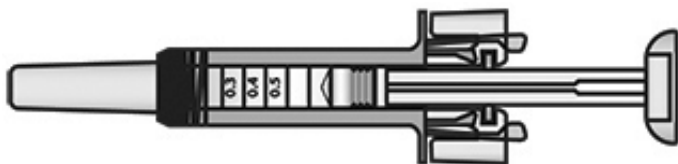


Figure D shows a needle guard that has not yet been activated. The prefilled syringe is ready for use.

Figure D Ready to Use



Step 9: Choose the injection site:

- Areas of your body that you may use as injection sites include:
 - the front of your thighs (**see Figure E**)
 - the lower stomach-area (abdomen), but not the area 2 inches around your navel (belly button) (**see Figure E**)
 - if a caregiver is giving you the injection
 - upper outer arms (**see Figure E and Figure F**)
 - upper areas of the buttocks (**see Figure F**)
- Choose a different site each time you give yourself an injection.
- **Do not** inject into areas where the skin is tender, bruised, red, scaly, or hard. Avoid areas with scars or stretch marks.

Figure E

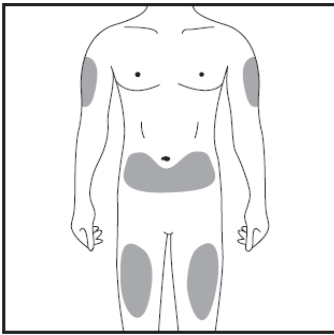
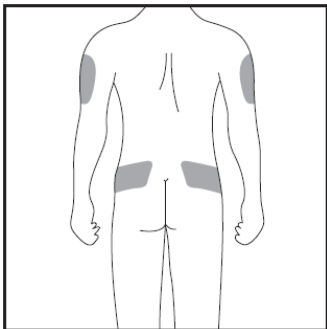


Figure F



Step 10. Clean the injection site using a circular motion with the alcohol wipe. Leave it to dry before injecting.
Do not touch the cleaned area again before injecting.

Giving your injection

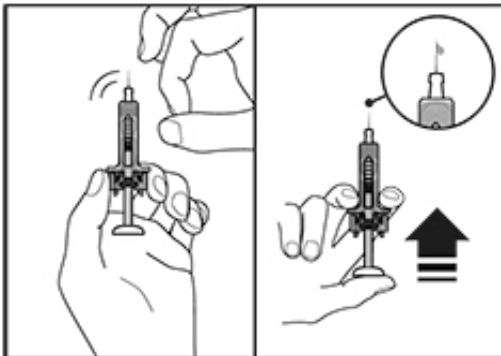
Step 11. Hold the prefilled syringe by the body (the clear plastic needle guard) with the needle pointing up (see **Figure G**). Holding the syringe with the needle pointing up helps to prevent medicine from leaking out of the needle. Carefully pull the needle cap straight off. Throw away the needle cap.

Figure G



Step 12. Check the syringe for an air bubble. Gently tap the syringe with your fingers until the air bubble rises to the top of the syringe (see **Figure H**). Slowly push the plunger up to push any air out of the syringe and stop when you see a small drop start to appear at the needle tip (see **Figure H**).

Figure H



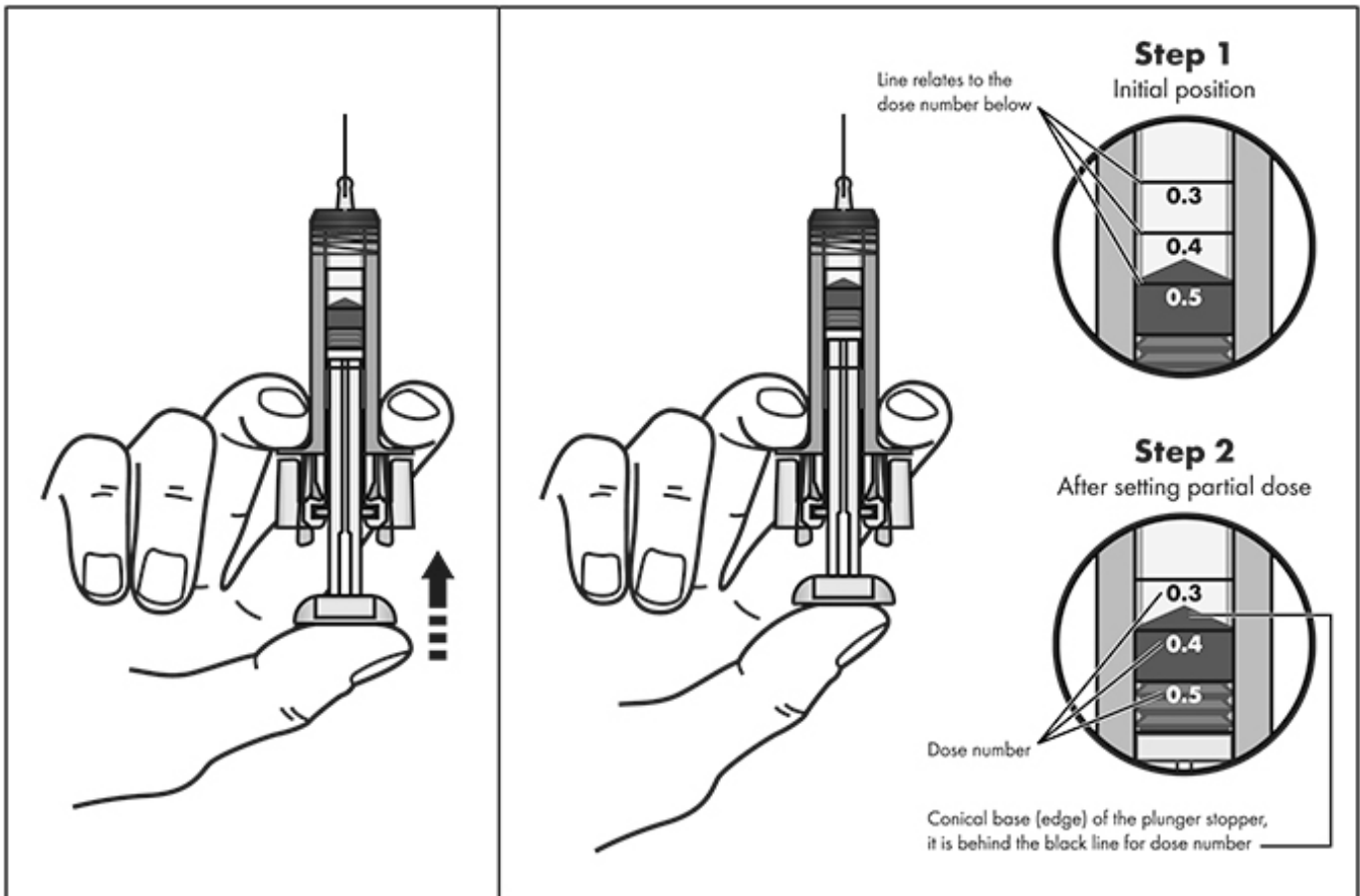
Step 13. Holding the syringe as shown, press slowly on the plunger to push out the excess medicine until the edge of the conical base of the plunger stopper lines up with the syringe marking for your prescribed dose. See **Figure I**, example for a dose of 0.4 mL.

Be careful not to touch the needle guard wings before use. The needle guard may be activated too early.

Check again to make sure the correct dose of ZARXIO is in the syringe.

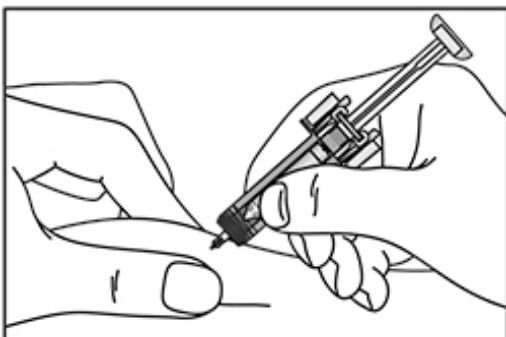
Call your healthcare provider or nurse if you have problems measuring or injecting your dose of ZARXIO.

Figure I



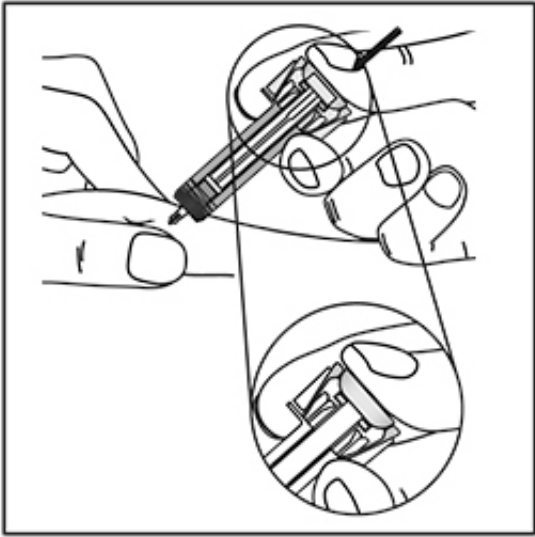
Step 14. With one hand gently pinch the skin at the injection site. With your other hand insert the needle into your skin as shown (**see Figure J**). Push the needle all the way in to make sure that you inject your full dose.

Figure J



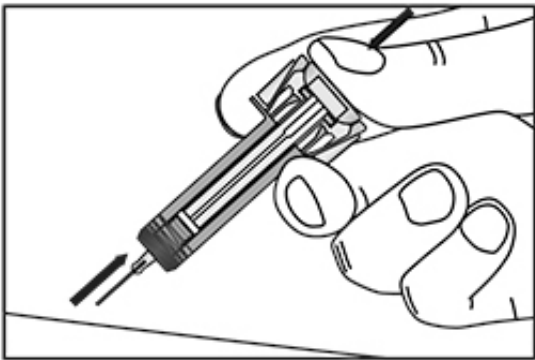
Step 15. Hold the ZARXIO prefilled syringe as shown (see **Figure K**). Slowly press down on the plunger as far as it will go so that the plunger head is completely between the needle guard wings.

Figure K



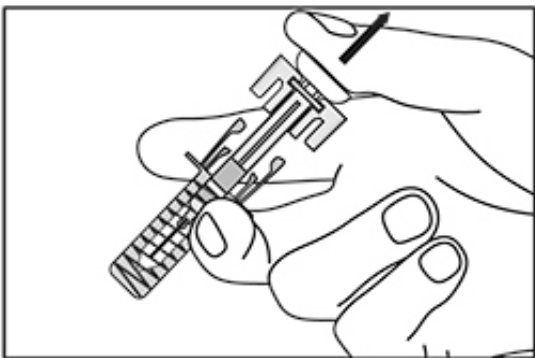
Step 16. Keep the plunger fully pressed down while you carefully pull the needle straight out from the injection site (see **Figure L**).

Figure L



Step 17. Slowly release the plunger and allow the needle guard to automatically cover the exposed needle (see **Figure M**).

Figure M



Step 18. There may be a small amount of blood at the injections site. You can press a cotton ball or gauze over the injection site and hold it for 10 seconds. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if needed.

How should I dispose of (throw away) used ZARXIO prefilled syringes?

Put your used prefilled syringes in a FDA-cleared sharps disposal container right away after use (see Figure N). Do not throw away (dispose of) ZARXIO prefilled syringes in your household trash.

Figure N



If you do not have an 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, syringes, and prefilled 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 syringe, or sharps disposal container or throw them into household trash.

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

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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