



LEARN

— *about* —



ZARXIO[®] (filgrastim-sndz)

Subcutaneous or Intravenous Injection
300 mcg/0.5 mL | 480 mcg/0.8 mL

Please see Important Safety Information on pages 3-5
and enclosed full Prescribing Information.



What is ZARXIO® (filgrastim-sndz)?

ZARXIO is a man-made form of granulocyte colony-stimulating factor (G-CSF) called filgrastim. G-CSF is a substance produced by the body. It stimulates the growth of neutrophils, a type of white blood cell important in the body's fight against infection.

Some cancer treatments decrease white blood cell counts, increasing the risk of infection. A low level of neutrophils is known as neutropenia.

When receiving strong chemotherapy, ZARXIO may be appropriate.





What is a biosimilar?

ZARXIO is the first biosimilar approved in the US.

A biosimilar is a medication that has been approved by the FDA as being “highly similar” to a previously approved biologic medication. Biosimilars may be available at a lower cost than the referenced biologic medication.



What is ZARXIO approved to treat?

ZARXIO is a prescription medicine used to help reduce the chance of infection due to a low white blood cell count in people with certain types of cancer (non-myeloid) who receive anti-cancer medicines (chemotherapy) that can cause fever and a low blood cell count.



What else do I need to know about ZARXIO?

In the following pages of this brochure, you’ll find information about how ZARXIO is administered.

If you have additional questions, please consult your healthcare provider or nurse.

IMPORTANT SAFETY INFORMATION

Do not take ZARXIO if you have had a serious allergic reaction to human G-CSFs such as filgrastim or pegfilgrastim products.

Please see additional Important Safety Information on pages 4 and 5 and enclosed full Prescribing Information.

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IMPORTANT SAFETY INFORMATION (cont'd)

Before you take ZARXIO, tell your doctor about all of your medical conditions, including if you:

- have a sickle cell disorder.
- have a problem with your kidneys, as you may need more frequent urine tests.
- are receiving radiation therapy.
- are allergic to latex. 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.
- are pregnant or plan to become pregnant. It is not known if ZARXIO will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if ZARXIO passes into your breast milk.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the possible side effects of ZARXIO?

ZARXIO may cause serious side effects, including:

- **Spleen rupture.** Your spleen may become enlarged and can rupture. A ruptured spleen can cause death. Call your doctor right away if you have pain in the left upper stomach (abdomen) area or your left shoulder.
- **A serious lung problem called acute respiratory distress syndrome (ARDS).** Call your doctor or get emergency medical help right away if you have shortness of breath with or without a fever, trouble breathing, or a fast rate of breathing.
- **Serious allergic reactions.** ZARXIO can cause serious allergic reactions. These reactions can cause a rash over your whole body, shortness of breath, wheezing, dizziness, swelling around your mouth or eyes, fast heart rate, and sweating. If you have any of these symptoms, stop using ZARXIO, and call your doctor or get emergency help right away.
- **Sickle cell crises.** You may have a serious sickle cell crisis if you have a sickle cell disorder and take ZARXIO. Serious sickle cell crisis has happened in people with sickle cell disorders receiving filgrastim that has sometimes led to death. Call your doctor right away if you have symptoms of sickle cell crisis such as pain or difficulty breathing.
- **Kidney injury (glomerulonephritis).** Kidney injury has been seen in patients who received ZARXIO. Call your doctor right away if you experience puffiness in your face or ankles, blood in your urine or brown-colored urine or you notice you urinate less than usual.

IMPORTANT SAFETY INFORMATION (cont'd)

- **Capillary leak syndrome.** ZARXIO can cause fluid to leak from blood vessels into your body's tissues. This condition is called "Capillary Leak Syndrome" (CLS). CLS can quickly cause you to have symptoms that may become life-threatening. Get emergency medical help right away if you develop any of the following symptoms:
 - swelling or puffiness and are urinating less often.
 - trouble breathing.
 - swelling of your stomach-area (abdomen) and feeling of fullness.
 - dizziness or feeling faint.
 - a general feeling of tiredness.
- **Myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML).**
 - ZARXIO may increase the risk of developing a precancerous condition called MDS or a type of blood cancer called AML in people who were born with low white blood cell counts (congenital neutropenia).
 - If you have breast cancer or lung cancer, when ZARXIO is used with chemotherapy and radiation therapy, or with radiation therapy only, you may have an increased risk of developing MDS or AML.
 - Symptoms of MDS and AML may include tiredness, fever, and easy bruising or bleeding.
 - Call your healthcare provider if you develop any of these symptoms during treatment with ZARXIO.
- **Decreased platelet count (thrombocytopenia).** Your doctor will check your blood during treatment with ZARXIO. Tell your doctor if you have unusual bleeding or bruising while taking ZARXIO. This could mean a decrease of platelets, which reduces the ability of blood to clot.
- **Increased white blood cell count (leukocytosis).** Your doctor will check your blood during treatment with ZARXIO.
- **Inflammation of your blood vessels (cutaneous vasculitis).** Tell your doctor if you develop purple spots or redness of your skin.
- **Inflammation of the aorta (aortitis).** Inflammation of the aorta (the large blood vessel which transports blood from the heart to the body) has been reported in patients who received filgrastim products. Symptoms may include fever, abdominal pain, feeling tired, and back pain. Call your healthcare provider if you experience these symptoms.

The most common side effects of ZARXIO include aching in the bones and muscles.

These are not all the possible side effects of ZARXIO. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.



Please see enclosed full Prescribing Information.



How is ZARXIO administered?

ZARXIO injections can be given by a healthcare provider or nurse by intravenous (IV) infusion or under your skin (subcutaneous injection). Your healthcare provider may decide subcutaneous injections can be given at home by you or your caregiver. If ZARXIO is given at home, see the detailed Instructions for Use that come with your prescription for information on how to prepare and inject a dose of ZARXIO.

You and your caregiver will be shown how to prepare and inject ZARXIO before you use it.



How do I administer a ZARXIO injection?

Your healthcare provider will provide you with training on how to inject ZARXIO. They will explain what dose you should administer and how frequently it should be injected. You should not attempt to give yourself a subcutaneous injection until you have received the appropriate training from your healthcare provider.



How do I prepare for a ZARXIO injection?

In addition to the prefilled syringe that is included in your pack, you will need

- 1 alcohol wipe
- 1 cotton ball or gauze
- Sharps disposal container
- 1 adhesive bandage

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.



How should I store ZARXIO?

- Store ZARXIO in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Avoid freezing ZARXIO. If frozen, thaw in the refrigerator before use. Throw away (dispose of) ZARXIO if it has been frozen more than 1 time.
- Store ZARXIO in the original pack to protect it from light.
- Do not shake 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 24 hours. **Throw away (dispose of) any ZARXIO that has been left at room temperature for longer than 24 hours.**
- 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.

Please see Important Safety Information on pages 3-5 and enclosed full Prescribing Information.

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When you are ready to administer the injection, follow these steps:

INJECTION SETUP

- 1 Find a clean, well-lit, flat work surface.
- 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.
- 3 Wash your hands well with soap and water.

IMPORTANT REMINDERS

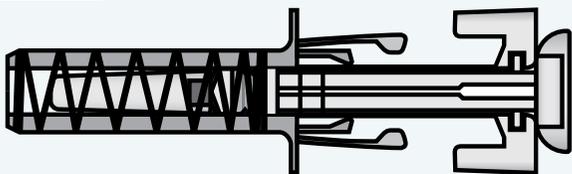
- **Do not inject yourself or someone else until you have been shown how to inject ZARXIO.** Your healthcare provider or nurse will show you how to prepare and inject ZARXIO properly using the ZARXIO prefilled syringe with UltraSafe Passive™ Needle Guard. Talk to your healthcare provider or nurse if 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 do I dispose of (throw away) used ZARXIO prefilled syringes?” on page 15.

Please review the complete Instructions for Use in the enclosed Package Insert.

DOSE PREPARATION

- 4 Remove the ZARXIO prefilled syringe from the outer pack and take it out of the blister.
- 5 Check the expiration date. Do not use the ZARXIO prefilled syringe if the expiration date has passed.
- 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. If this occurs, instead return the ZARXIO prefilled syringe and the package it came in to your pharmacy.
- 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.
- 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 A), 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 B).

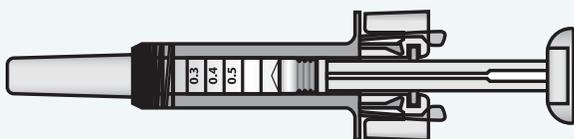
FIGURE A



Do not use: Figure A shows a needle guard that has already been activated.

Do not use a ZARXIO prefilled syringe that has been activated.

FIGURE B



Ready to use: Figure B shows a needle guard that has not yet been activated. The prefilled syringe is ready to use.

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PREPARING THE INJECTION SITE

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Choose your injection site. Areas of your body that you may use as injection sites include:

- The front of your thighs (see **Figure C**)
- The lower stomach area (abdomen), but not the area 2 inches around your navel (belly button) (see **Figure C**)
- If a caregiver is giving you the injection:
 - Upper outer arms (see **Figure C and Figure D**)
 - Upper areas of the buttocks (see **Figure D**)
- Choose a different site for each injection of ZARXIO
- **Do not** inject into areas where the skin is tender, bruised, red, scaly, or hard
- Avoid areas with scars or stretch marks

FIGURE C

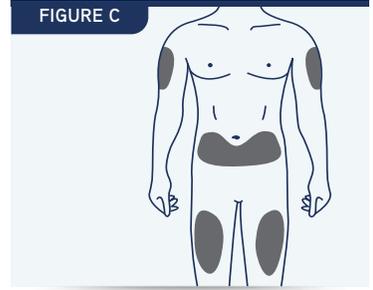
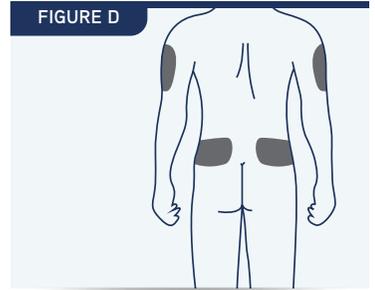


FIGURE D



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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.

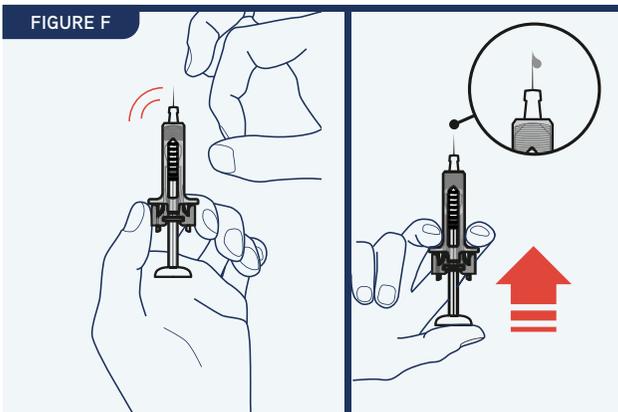


GIVING YOUR INJECTION

- 11** Hold the prefilled syringe by the body (the clear plastic needle guard) with the needle pointing up (see **Figure E**). 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.



- 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 F**). 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 F**).



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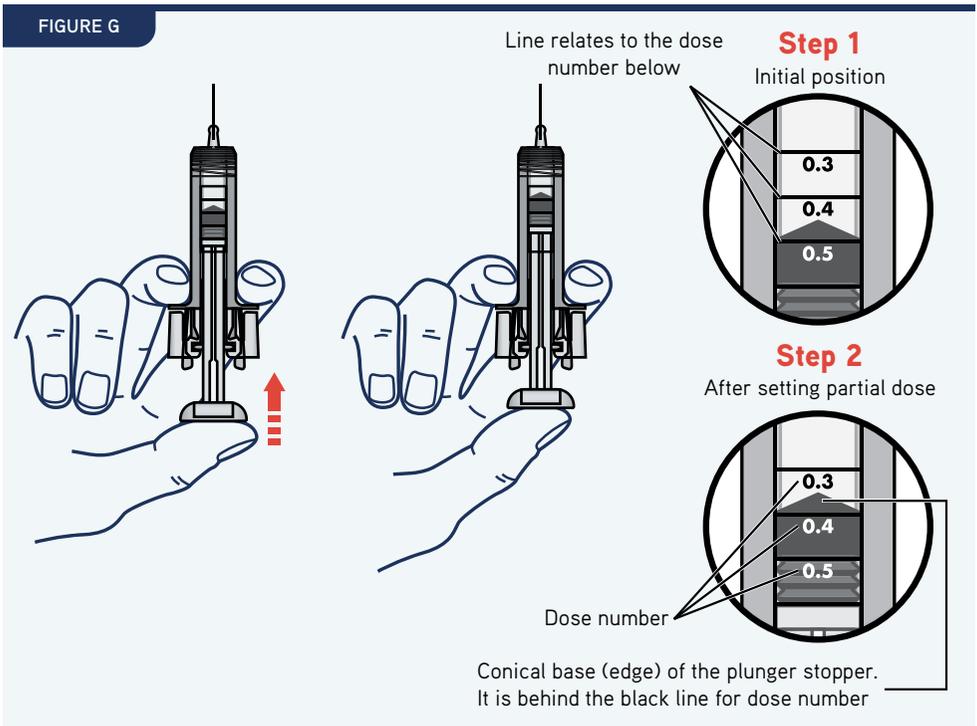
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Holding the syringe as shown, press slowly on the plunger to push out the excess medicine until the edge of the conical base of the plunger stopper lines up with the syringe marking for your prescribed dose. See **Figure G**, example for a dose of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

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

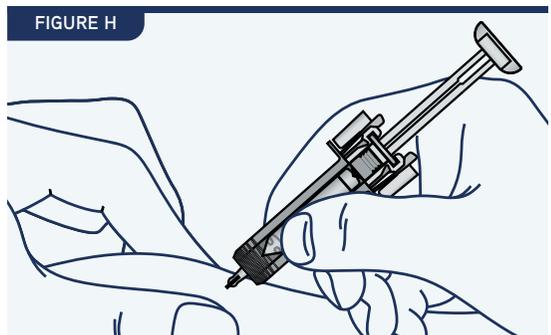
Check again to make sure the correct dose of ZARXIO is in the syringe.

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

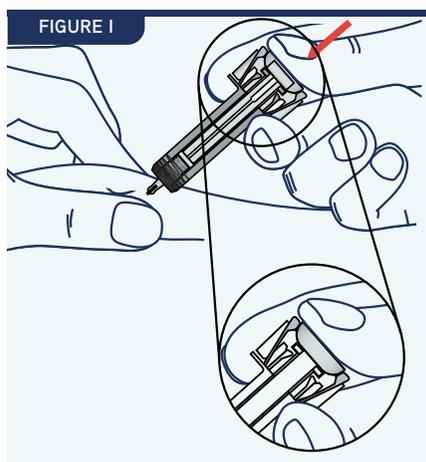


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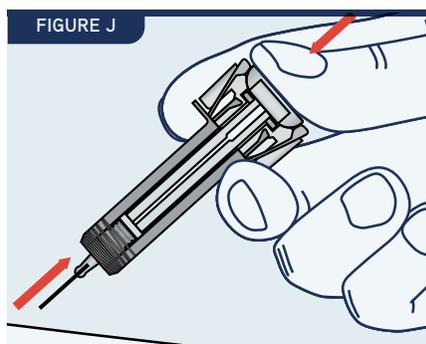
With one hand, gently pinch the skin at the injection site. With your other hand, insert the needle into your skin as shown (see **Figure H**). Push the needle all the way in to make sure you inject your full dose.



- 15** Hold the ZARXIO prefilled syringe as shown (**see Figure I**). Slowly press down on the plunger as far as it will go so that the plunger head is completely between the needle guard wings. Keep the plunger pressed fully down while you hold the syringe in place for 5 seconds.



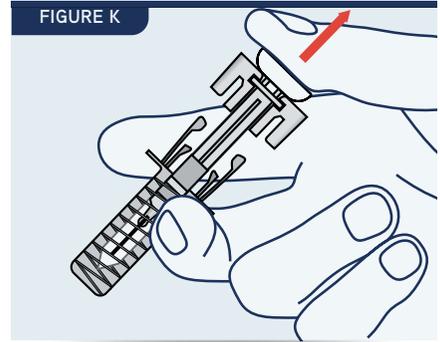
- 16** Keep the plunger fully pressed down while you carefully pull the needle straight out from the injection site (**see Figure J**).



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- 17 Slowly release the plunger and allow the needle guard to automatically cover the exposed needle (see Figure K).



- 18 There may be a small amount of blood at the injection 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 do I dispose of (throw away) used ZARXIO prefilled syringes?

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.

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

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,
- Is upright and stable during use,
- Is leak-resistant, and
- Is 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.

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Some possible questions for your healthcare provider about ZARXIO



Open communication with your healthcare team is an important way to make sure that you are getting the most out of your treatment. If your healthcare provider has prescribed ZARXIO, you might want to ask the following questions:

Why have you prescribed ZARXIO as part of my treatment plan?

What are the most common side effects I might develop while taking ZARXIO?

What are the risks and benefits of taking ZARXIO?



How long will I have to take ZARXIO?

Are there any other steps I should take to prevent infections and other complications from neutropenia?

Please see Important Safety Information on pages 3-5 and enclosed full Prescribing Information.





You can receive your first and subsequent doses of ZARXIO at no cost*

Sandoz One Source: Patient Support Services

Sandoz One Source provides comprehensive patient support services designed to help simplify and support patient access.

- Benefit investigations
- Prior authorization support
- Appeals support
- Commercial Co-Pay Program
- Independent foundation information
- Patient Assistance Program
- Reimbursement support
- In-home injection training

\$0 out-of-pocket for **first dose or cycle**

\$0 out-of-pocket for **subsequent doses or cycles**

- For eligible,*commercially insured patients
- No income requirements
- Virtual co-pay card ensures that patients have immediate access to their benefits

*Eligibility Requirements: Maximum benefit of \$10,000 annually. Prescription must be for an approved indication. This program is not health insurance. This program is for insured patients only; cash-paying or uninsured patients are not eligible. Patients are not eligible if prescription for ZARXIO is paid, in whole or in part, by any state or federally funded programs, including but not limited to Medicare (including Part D, even in the coverage gap) or Medicaid, Medigap, VA, DOD, or TRICARE, or private indemnity plans that do not cover prescription drugs, or HMO insurance plans that reimburse the patient for the entire cost of their prescription drugs, or where prohibited by law. Co-Pay Program may apply to out-of-pocket expenses that occurred within 120 days prior to the date of the enrollment. Co-Pay Program may not be combined with any other rebate, coupon, or offer. Co-Pay Program has no cash value. Sandoz reserves the right to rescind, revoke, or amend this offer without further notice.

To learn more about Sandoz One Source, call
1-844-SANDOZ1 (1-844-726-3691), option 2
or go to **www.zarxio.com**

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