

Patient Information
ZIEXTENZO™ (zee-eks-TEN-zoh)
(pegfilgrastim-bmez)
injection
Single-dose prefilled syringe

What is ZIEXTENZO?

ZIEXTENZO is a man-made form of granulocyte colony-stimulating factor (G-CSF). 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.

Do not take ZIEXTENZO if you have had a serious allergic reaction to pegfilgrastim products or filgrastim products.

Before you receive ZIEXTENZO, tell your healthcare provider about all of your medical conditions, including if you:

- have a sickle cell disorder.
- have kidney problems.
- are allergic to latex. The needle cap on the prefilled syringe contains dry natural rubber (made from latex). You should not inject ZIEXTENZO using the prefilled syringe if you have latex allergies.
- are pregnant or plan to become pregnant. It is not known if ZIEXTENZO will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if ZIEXTENZO passes into your breast milk.

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

How will I receive ZIEXTENZO?

- **ZIEXTENZO is given as an injection under your skin (subcutaneous injection) by a healthcare provider. If your healthcare provider decides that the subcutaneous injections can be given at home by you or your caregiver, follow the detailed "Instructions for Use" that comes with your ZIEXTENZO for information on how to prepare and inject a dose of ZIEXTENZO.**
- You and your caregiver will be shown how to prepare and inject ZIEXTENZO before you use it.
- You should not inject a dose of ZIEXTENZO to children weighing less than 45 kg from a ZIEXTENZO prefilled syringe. A dose less than 0.6 mL (6 mg) cannot be accurately measured using the ZIEXTENZO prefilled syringe.
- If you are receiving ZIEXTENZO because you are also receiving chemotherapy, the last dose of ZIEXTENZO should be injected at least 14 days before and 24 hours after your dose of chemotherapy.
- If you miss a dose of ZIEXTENZO, talk to your healthcare provider about when you should give your next dose.

What are possible side effects of ZIEXTENZO?

ZIEXTENZO may cause serious side effects, including:

- **Spleen Rupture.** Your spleen may become enlarged and can rupture. A ruptured spleen can cause death. Call your healthcare provider right away if you have pain in the left upper stomach area or your left shoulder.
- **A serious lung problem called Acute Respiratory Distress Syndrome (ARDS).** Call your healthcare provider or get emergency 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.** ZIEXTENZO 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 ZIEXTENZO and call your healthcare provider or get emergency medical help right away.
- **Sickle cell crises.** You may have a serious sickle cell crisis, which could lead to death, if you have a sickle cell disorder and receive ZIEXTENZO. Call your healthcare provider right away if you have symptoms of sickle cell crisis such as pain or difficulty breathing.
- **Kidney injury (glomerulonephritis).** ZIEXTENZO can cause kidney injury. Call your healthcare provider right away if you develop any of the following symptoms:
 - swelling of your face or ankles
 - blood in your urine or dark colored urine
 - you urinate less than usual
- **Increased white blood cell count (leukocytosis).** Your healthcare provider will check your blood during treatment with ZIEXTENZO.
- **Capillary Leak Syndrome.** ZIEXTENZO 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 than usual
 - trouble breathing

- swelling of your stomach area (abdomen) and feeling of fullness
- dizziness or feeling faint
- a general feeling of tiredness
- **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 pegfilgrastim. 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 ZIEXTENZO are pain in the bones, arms, and legs.

These are not all the possible side effects of ZIEXTENZO.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ZIEXTENZO?

- Store ZIEXTENZO in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Take ZIEXTENZO out of the refrigerator for at least 15 to 30 minutes before use and allow it to reach room temperature before preparing an injection.
- Avoid freezing. If ZIEXTENZO is accidentally frozen, allow the prefilled syringe to thaw in the refrigerator before injecting.
- **Do not** use a ZIEXTENZO prefilled syringe that has been frozen more than 1 time. Use a new ZIEXTENZO prefilled syringe.
- Keep the prefilled syringe in the original carton to protect from light or physical damage.
- Do not shake the prefilled syringe.
- Throw away (dispose of) any ZIEXTENZO that has been left at room temperature, 68°F to 77°F (20°C to 25°C), for more than 72 hours.

Keep the ZIEXTENZO prefilled syringe out of the reach of children.

General information about the safe and effective use of ZIEXTENZO.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ZIEXTENZO for a condition for which it was not prescribed. Do not give ZIEXTENZO to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about ZIEXTENZO that is written for health professionals.

What are the ingredients in ZIEXTENZO?

Active ingredient: pegfilgrastim-bmez

Inactive ingredients: acetic acid, polysorbate 20, sorbitol, and Water for Injection. Sodium hydroxide may be added as necessary to adjust pH.

Manufactured by: Sandoz Inc. Princeton, NJ 08540 US License No. 2003

Product of Slovenia.

For more information, visit www.ziextenzo.com or call 1-800-525-8747

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(pegfilgrastim-bmez)
injection
Single-dose prefilled syringe

Guide to Parts

Before use

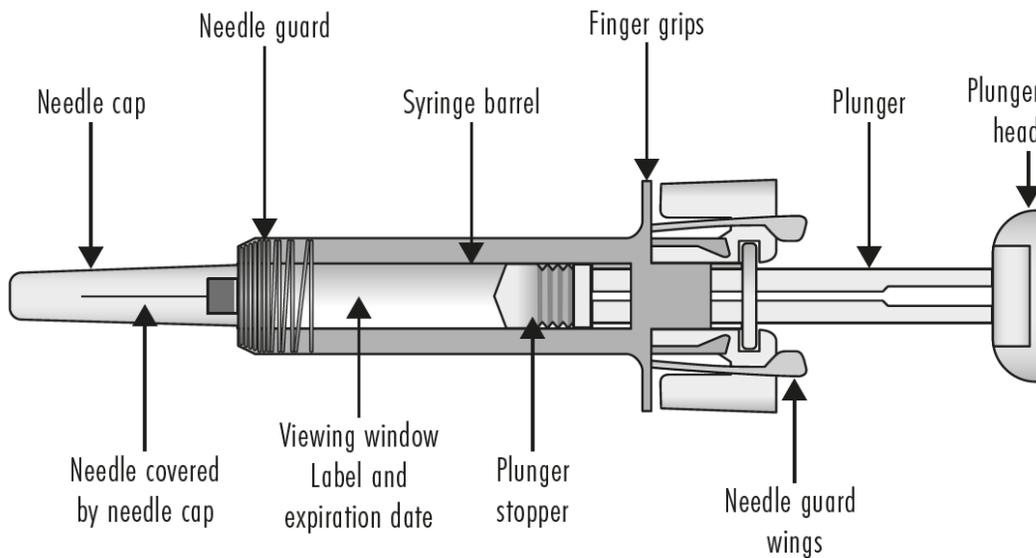


Figure A: Before use. The ZIEXTENZO prefilled syringe with needle guard not activated

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

After use

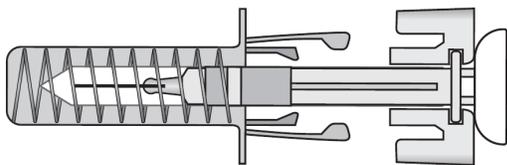


Figure B: After Use. The ZIEXTENZO prefilled syringe with needle guard activated.

Important information:

Read the Patient Information that comes with ZIEXTENZO for important information you need to know about ZIEXTENZO before using these Instructions for Use.

Storing the ZIEXTENZO prefilled syringe

- Store ZIEXTENZO in a refrigerator between 36°F to 46°F (2°C to 8°C).
- Store ZIEXTENZO prefilled syringe in its outer carton to protect it from light or physical damage.
- Take ZIEXTENZO out of the refrigerator at least 15 to 30 minutes before use to allow it to reach room temperature before preparing the injection.
- Avoid freezing. If ZIEXTENZO is accidentally frozen, thaw in the refrigerator before injecting.
- **Do not** use a ZIEXTENZO prefilled syringe that has been frozen more than 1 time. Use a new ZIEXTENZO prefilled syringe.
- Throw away (dispose of) any ZIEXTENZO that has been left at room temperature 68°F to 77°F (20°C to 25°C) for more than 72 hours. **See “14. Disposing of used prefilled syringes”.**

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

Important information:

- **It is important that you do not try to give the injection unless you or your caregiver have received training from your healthcare provider.**
- The needle cap on the prefilled syringe contains natural rubber (made from latex). **Tell your healthcare provider if you are allergic to latex. Do not handle the prefilled syringe if you are allergic to latex.**
- Make sure that the name ZIEXTENZO appears on the carton and prefilled syringe label.
- Check the carton and prefilled syringe label to make sure the dose strength is 6 mg/0.6 mL.
- You should not inject a dose of ZIEXTENZO to children weighing less than 45 kg from a ZIEXTENZO prefilled syringe. A dose less than 0.6 mL (6 mg) cannot be accurately measured using the ZIEXTENZO prefilled syringe.
- **Do not** use a ZIEXTENZO prefilled syringe after the expiration date on the label.
- **Do not** open the outer carton until you are ready to use the ZIEXTENZO prefilled syringe. **Do not** use the ZIEXTENZO prefilled syringe if the seal of the tray is broken, as it may not be safe for you to use.
- **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** shake the ZIEXTENZO prefilled syringe.
- Be careful not to touch the needle guard wings before use. Touching them may cause the needle guard to be activated too early.
- **Do not** try to activate the needle safety guard before the injection.
- **Do not** remove the needle cap until just before you give the injection.
- **Do not reuse** a ZIEXTENZO prefilled syringe. Throw away (dispose of) used prefilled syringes right away after use in a sharps disposal container. **See “14. Disposing of used prefilled syringes”.**

Call your healthcare provider if you have any questions.

Prepare the injection.

1. Find a clean, flat, well-lit work surface.
2. Remove the carton from the refrigerator and check the expiration date printed on the carton.
3. Remove the tray containing a ZIEXTENZO prefilled syringe from the carton and place it unopened on your clean work surface for at least 15 to 30 minutes, so that it can reach room temperature.
 - **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 a microwave.
 - **Do not** leave the prefilled syringe in direct sunlight.
 - **Do not** shake the prefilled syringe.
4. Wash your hands well with soap and water.

Gather the following supplies for the injection (See Figure C):

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



Figure C

5. Open the tray by peeling away the cover. Remove the ZIEXTENZO prefilled syringe from the tray by grabbing the transparent safety guard (**See Figure D**).

For safety reasons:

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

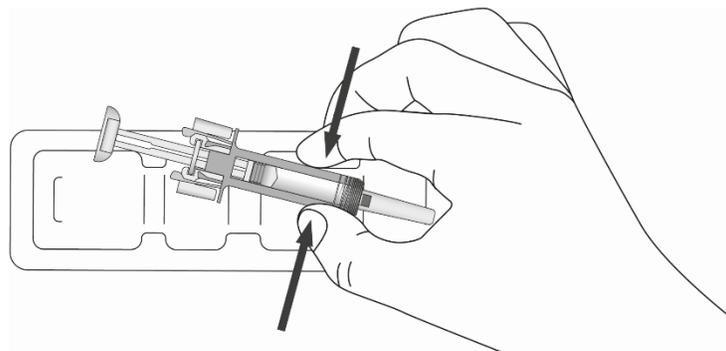


Figure D

Check to be sure that the plastic clear needle guard is located over the barrel of the glass syringe. If the clear needle guard is covering the needle cap, as shown in Figure B above, the needle guard has been activated. **Do not try to use this prefilled syringe.** Throw away (dispose of) this prefilled syringe. **See “14. Disposing of used prefilled syringes”.** Start over with a new prefilled syringe.

Inspect the prefilled syringe and medicine (See Figure E).

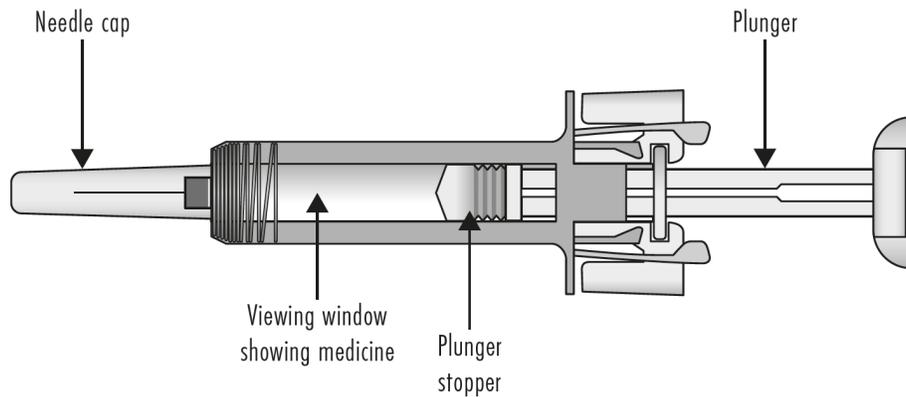


Figure E

6. Make sure that the medicine in the prefilled syringe is clear and colorless to slightly yellowish. You may see small air bubbles in the liquid. This is normal.

Do not use the prefilled syringe if:

- the medicine looks discolored or cloudy
- the medicine contains lumps, flakes, or particles
- it appears used or damaged
- the 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.

Select and clean the injection site

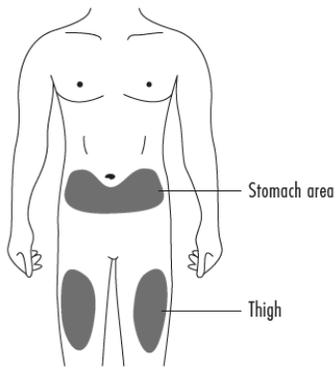


Figure F

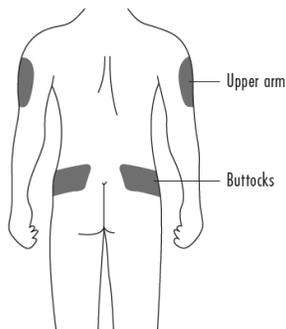


Figure G

You can use (**See Figure F and Figure G**):

- the front of your thighs
- stomach-area (abdomen), except for a **2** inch area right around the navel (belly button)
- upper outer area of the buttocks (only if someone else is giving you the injection)
- outer area of upper arm (only if someone else is giving you the injection)

Choose a different site each time you give yourself an injection. **Do not** inject again in the exact same spot.

Do not inject into areas where the skin is tender, bruised, red, scaly or hard. Avoid areas with scars or stretch marks.

7. Clean the injection site with an alcohol wipe. Let the skin dry. Do not touch the cleaned area again before injecting.

Prepare the ZIEXTENZO prefilled syringe for use

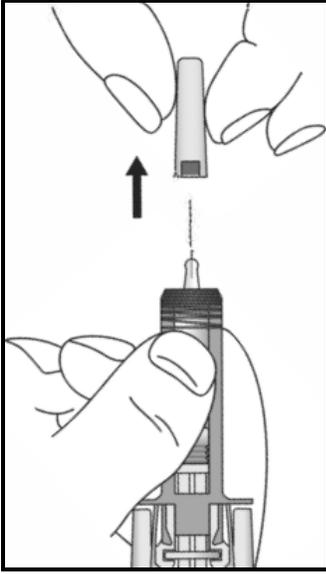


Figure H

8. Hold the prefilled syringe by the syringe barrel. Carefully pull the needle cap straight off to remove it from the ZIEXTENZO prefilled syringe (**See Figure H**).
- **Do not** twist or bend the gray needle cap.
 - **Do not** hold the prefilled syringe by the plunger rod.

Throw away the needle cap in your household trash. **Do not** put the needle cap back onto the prefilled syringe.

You may see a drop of liquid at the end of the needle. This is normal.

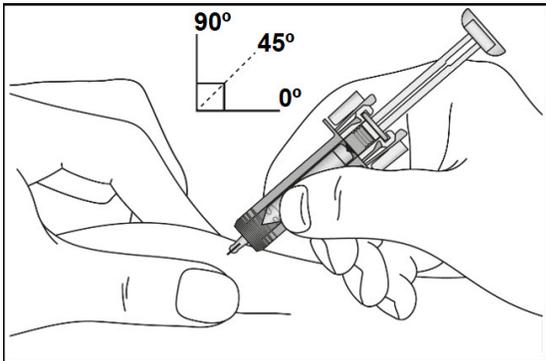


Figure I

9. With your other hand, gently pinch the skin at the injection site to create a firm surface. Insert the needle into the skin at an angle of 45 to 90 degrees, as shown (**See Figure I**). Push the needle all the way in to ensure that the medicine can be fully injected.

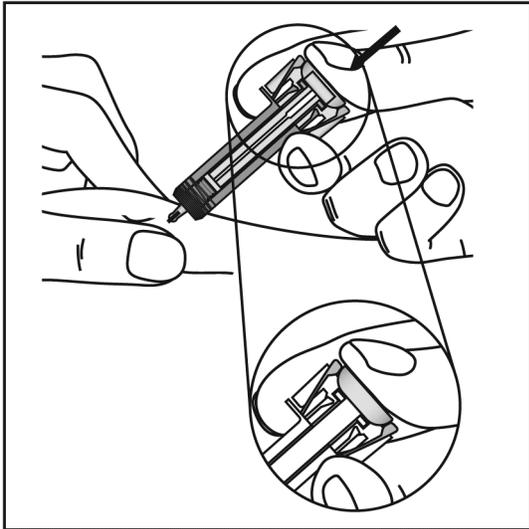


Figure J

10. Hold the ZIEXTENZO prefilled syringe as shown (**See Figure J**). Slowly press down the plunger head as far as it will go until the plunger head is completely between the needle guard wings.

Important: Keep the skin pinched while injecting.

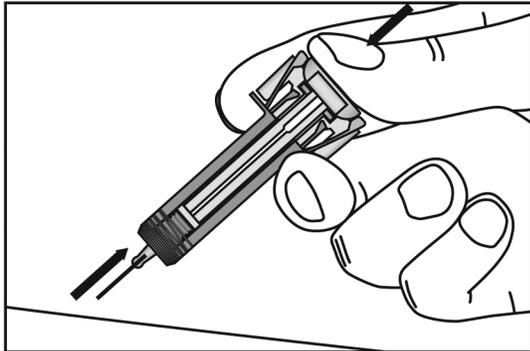


Figure K

11. Keep the plunger fully pressed down while you carefully pull the needle straight out from the injection site and off your skin (**See Figure K**).

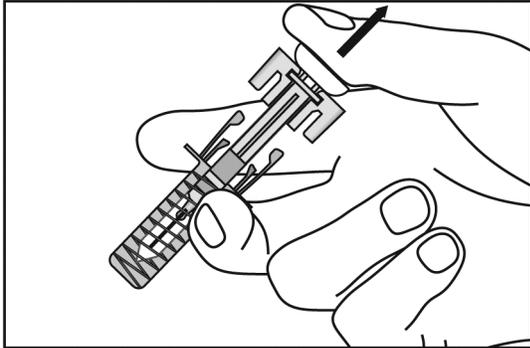


Figure L

12. Slowly release the plunger and allow the syringe needle guard to automatically cover the exposed needle (**See Figure L**).

13. There may be a small amount of blood at the injection site. You can press a cotton ball or gauze pad onto the injection site. Do not rub the injection site. Apply an adhesive bandage if needed.

14. Disposing of used prefilled syringes

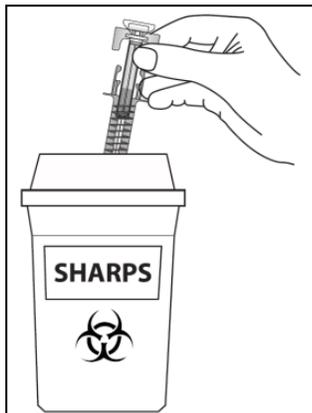


Figure M

Put the used prefilled syringes in an FDA-cleared sharps disposal container right away after use (**See Figure M**). **Do not** throw away the syringe in the 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
 - upright and stable during use
 - leak-resistant
 - 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 prefilled syringes or sharps disposal container or throw them into household trash.

Important: 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.

Manufactured by: Sandoz Inc. Princeton, NJ 08540

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Issued: August/2019