

INSTRUCTIONS FOR USE
WEZLANA™ (wez-LAH-nah)
(ustekinumab-auub)
injection, for subcutaneous use
single-dose vial

This Instructions for Use contains information on how to inject WEZLANA using a vial.

Read this Instructions for Use before you start using WEZLANA. A healthcare provider should show you how to prepare, measure the dose, and give the injection the right way.

If you cannot give the injection:

- ask a healthcare provider to help you, or
- ask someone who has been trained by a healthcare provider to give the injections.

Do not try to inject WEZLANA until you have been shown the right way to give the injections by a healthcare provider.

Important information You Need to Know Before Injecting WEZLANA:

- **For subcutaneous use only** (inject directly under the skin).
- Before you start, check the carton to make sure that it is the right dose. You will have either 45 mg or 90 mg as prescribed by the healthcare provider.
 - If the dose is 45 mg or less, you will receive one 45 mg vial.
 - If the dose is 90 mg, you will receive two 45 mg vials **and you will need to give two injections, one right after the other.**
- Check the expiration date on the vial and carton. If the expiration date has passed, do not use it. If the expiration date has passed, call the healthcare provider or pharmacist, or call 1-800-77-AMGEN (1-800-772-6436) for help.
- Check the vial for any particles or discoloration. The liquid in the vial should look clear to white like an opal and colorless to light yellow.
- Do not use if it is frozen, discolored, cloudy or has large particles. Get a new vial.
- **Do not shake the vial at any time.** Shaking the vial may damage the WEZLANA medicine. If the vial has been shaken, do not use it. Get a new vial.
- Do not use a WEZLANA vial more than one time, even if there is medicine left in the vial. After the rubber stopper is punctured, WEZLANA can become contaminated by harmful bacteria which could cause an infection if re-used. Therefore, throw away any unused WEZLANA after you give the injection.
- Safely throw away (dispose of) WEZLANA vials, needles, and syringes after use. See **“Step 6: Disposing of needles, syringes, and vials.”**
- Do not re-use syringes or needles.
- To avoid needle-stick injuries, **do not** recap needles.

Storing WEZLANA vials

- Store WEZLANA vials in a refrigerator between 36°F to 46°F (2°C to 8°C).
- Store WEZLANA vials in the original carton to protect from light until the time of use.
- **Do not** freeze WEZLANA vials.
- If needed, the WEZLANA vial can also be stored at room temperature up to 86°F (30°C) for a maximum single period of up to 30 days in the original carton to protect from light. Write the date that you removed WEZLANA from the refrigerator on the carton in the space provided.
- Do not use WEZLANA if it has been stored above 86°F (30°C).
- Do not put WEZLANA back in the refrigerator after it has been stored at room temperature.
- Throw away (discard) the vial if it is not used within 30 days of room temperature storage.

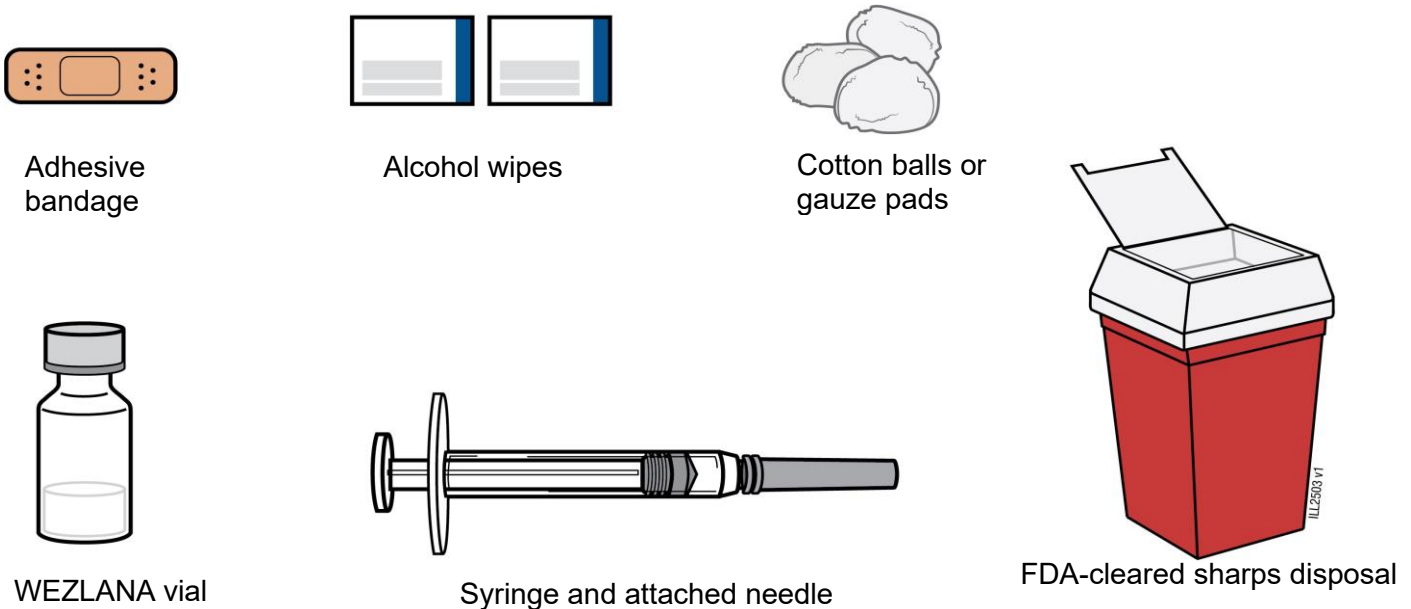
Keep WEZLANA and all medicines out of the reach of children.

Gather the supplies you will need to prepare WEZLANA and to give the injection. (See Figure A)

You will need:

- a syringe with the needle attached, you will need a prescription from a healthcare provider to get syringes with the needles attached from a pharmacy
- alcohol wipes
- cotton balls or gauze pads
- adhesive bandage
- your prescribed dose of WEZLANA
- FDA-cleared sharps disposal container. See “**Step 6: Dispose of the needles, syringes, and vials.**”

Figure A

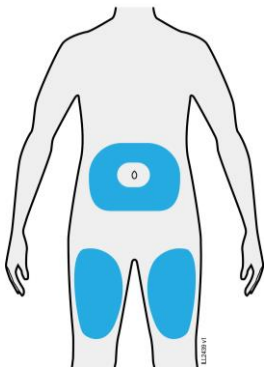


Step 1. Preparing the injection

- Choose a well-lit, clean, flat work surface.
- Wash your hands well with soap and warm water.

Step 2. Preparing your injection site

Figure B



* Areas in blue are recommended injection sites.

- Choose an injection site around the stomach area (abdomen), or upper legs (thighs).

- If a caregiver is giving the injection, the outer area of the upper arms, or the buttocks may also be used. **(See Figure B)**
- **Use a different injection site for each injection. Do not** give an injection in an area of the skin that is tender, bruised, red or hard.
- Clean the skin with an alcohol wipe where you plan to give the injection.
- **Do not** touch this area again before giving the injection. Let the skin dry before injecting.
- **Do not** fan or blow on the clean area.

Step 3. Preparing the vial

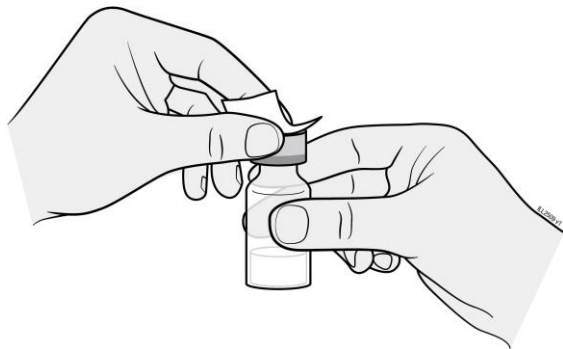
Figure C



3a

- Remove the cap from the top of the vial. Throw away the cap but do not remove the rubber stopper. **(See Figure C)**

Figure D

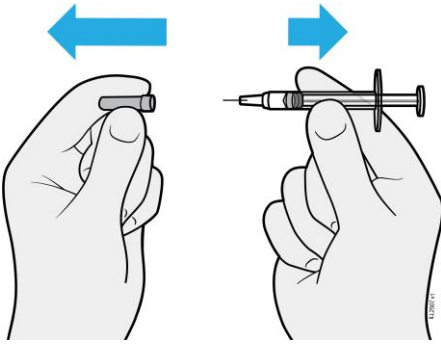


3b

- Clean the rubber stopper with an alcohol wipe. **(See Figure D)**
- Do not touch the rubber stopper after you clean it.
- Put the vial on a flat surface.

Step 4. Preparing the syringe

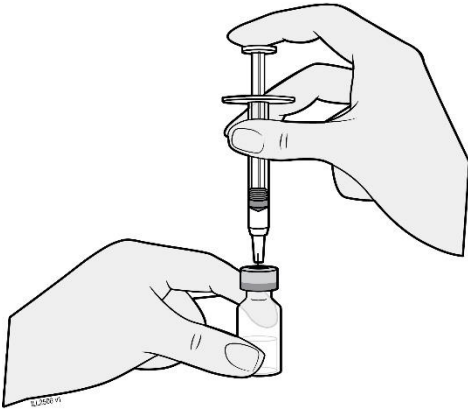
Figure E



4a

- Pick up the syringe with the needle attached.
- Remove the cap that covers the needle. **(See Figure E)**
- Throw the needle cap away. Do not touch the needle or allow the needle to touch anything.

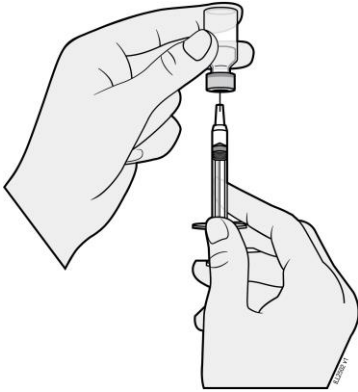
Figure F



4b

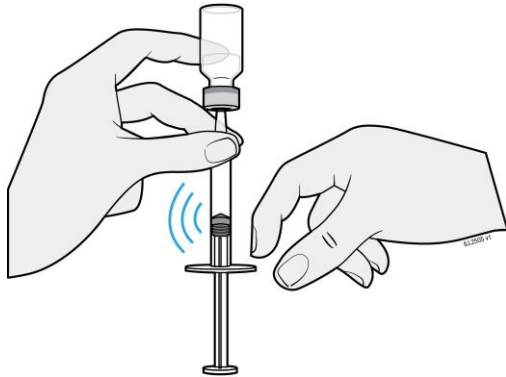
- Carefully pull back on the plunger to the line that matches the dose prescribed by the healthcare provider.
- Hold the vial between your thumb and index (pointer) finger.
- Use your other hand to push the syringe needle through the center of the rubber stopper. **(See Figure F)**

Figure G



- 4c**
- Push down on the plunger until all of the air has gone from the syringe into the vial.
 - Turn the vial and the syringe upside down. **(See Figure G)**
 - Hold the WEZLANA vial with one hand.
 - It is important that the needle is always in the liquid in order to prevent air bubbles forming in the syringe.
 - Pull back on the syringe plunger with your other hand.
 - Fill the syringe until the black tip of the plunger lines up with the mark that matches the prescribed dose.

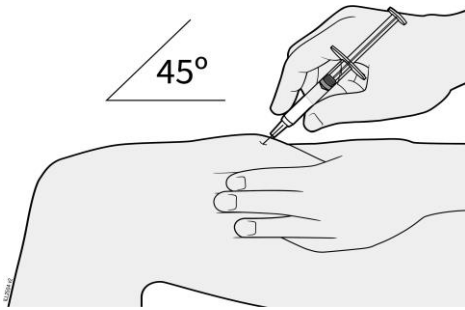
Figure H



- 4d**
- **Do not remove the needle from the vial.** Hold the syringe with the needle pointing up to see if it has any air bubbles inside.
 - If there are air bubbles, gently tap the side of the syringe until the air bubbles rise to the top. **(See Figure H)**
 - Slowly press the plunger up until all of the air bubbles are out of the syringe (but none of the liquid is out).
 - Remove the syringe from the vial. Do not lay the syringe down or allow the needle to touch anything.

Step 5. Injecting WEZLANA

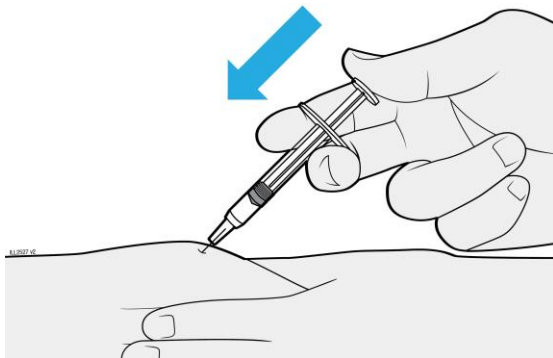
Figure I



5a

- Hold the barrel of the syringe in one hand, between the thumb and index fingers.
- **Do not** pull back on the plunger at any time.
- Use the other hand to gently pinch the cleaned area of skin. Hold firmly.
- Use a quick, dart-like motion to insert the needle into the pinched skin at about a 45-degree angle. (See Figure I)

Figure J



5b

- Push the plunger with your thumb as far as it will go to inject all of the liquid. Push it slowly and evenly, keeping the skin gently pinched. (See Figure J)
- When the syringe is empty, pull the needle out of the skin and then let go of the skin.
- When the needle is pulled out of the skin, there may be a little bleeding at the injection site. This is normal. You can press a cotton ball or gauze pad to the injection site if needed. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if necessary.

If the dose is 90 mg, you will receive two 45 mg vials and you will need to give a second injection right after the first. Repeat Steps 1 to 6 using a new syringe. Choose a different site for the second injection.

Step 6. Disposing of needles, syringes, and vials

- **Do not** re-use a syringe or needle.
- To avoid needle-stick injuries, do not recap a needle.
- Put the needles and syringes in an FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) loose needles and 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,
- 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 or state laws about how you should throw away syringes and needles. 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 dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your sharps disposal container.
- Throw away the vial into the container where you put the syringes and needles.
- If you have any questions, talk to your healthcare provider or pharmacist.

Manufactured for Nuvaila, Dublin, Ireland

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