

Instructions for Use
FUZEON™ (few'-zee-on)
(enfuvirtide)
Injection, for subcutaneous use
108 mg vial

1 Before You Begin

Important Information:

- Your healthcare provider should show you how to prepare and inject FUZEON before you inject it for the first time. **Do not** inject yourself or someone else until you have been shown how to inject FUZEON the right way.
- Call your healthcare provider if you have any questions about how to inject FUZEON the right way. You may also call 1-877-438-9366 or visit www.FUZEON.com.
- **Do not reuse or share syringes or needles with other people. You may give other people a serious infection or get a serious infection from them.**
- The instructions below are for mixing a single dose. If you want to mix 2 doses at the same time you will need 2 vials of FUZEON, 2 vials of sterile water, new sterile alcohol pads and syringes.

How should I store FUZEON?

- Store FUZEON vials that have not been mixed with sterile water at room temperature between 68°F to 77°F (20°C to 25°C).
- Store FUZEON that has been mixed with sterile water in the original vial and in the refrigerator between 36°F to 46°F (2°C to 8°C) for up to 24 hours. Throw away (discard) any unused FUZEON left in the vial after 24 hours.
- **Keep FUZEON and all medicines out of the reach of children.**

2 Getting Started

Gather Supplies:

Supplies you will need to give your FUZEON injection:

- A clean flat surface like a table
- One vial of FUZEON—at room temperature
- One 1 mL vial of sterile water
- One 3 mL (large) syringe with a 1-inch needle
- One 1 mL (small) syringe with a 1/2-inch needle
- Sterile alcohol pads (not supplied in this kit; may be obtained from your pharmacy)
- One sharps container for throwing away used syringes and needles. See “Disposing of your used syringes and needles” at the end of these instructions.



3 Prepare Your FUZEON Dose

- Check the expiration date printed on the FUZEON vial label.
- Check to make sure that none of the items in your kit have been opened.
- Check that the FUZEON vial is not cracked or damaged.
- **Do not use the FUZEON vial**, properly throw it away and get a new one if:
 - the expiration date printed on the FUZEON vial label has passed
 - the items in your FUZEON kit have been opened
 - the FUZEON vial is cracked or damaged

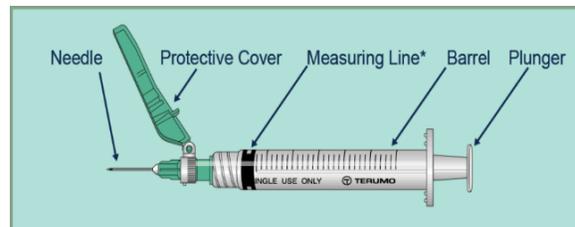
Step 1:

- Wash your hands well using soap and warm water and dry them with a clean towel.
- Once your hands are clean, **do not** touch anything other than the medicine, supplies and the area around the injection site.



Step 2:

- **Gather your syringes. You will need 2 syringes:**
 - One 3 mL (large) syringe for mixing FUZEON
 - One 1 mL (small) syringe for giving your FUZEON injection



The safety syringes have a green colored piece of plastic that is attached to the needle. This piece of plastic is a safety feature that covers the needle after use.

*The measuring line of the syringe is the edge line of the plunger closest to the needle.

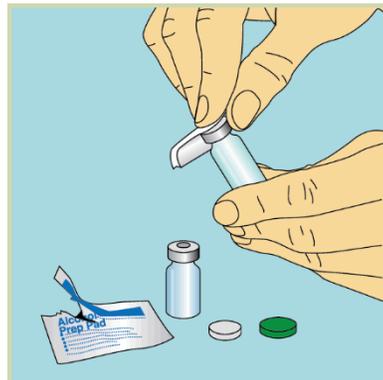
Your healthcare provider may recommend other types of syringes for use with FUZEON.

Step 3:

- Open the syringe packages, remove the syringes, and throw away the syringe packages.

Step 4:

- Take the caps off the vials and throw away the vial caps.
- Wipe each vial top with a new sterile alcohol pad and let the tops air-dry.
 - **Do not** touch the tops of the vials once they have been cleaned with an alcohol pad.
 - If you accidentally touch the rubber tops after cleaning them, clean them again with a new sterile alcohol pad.

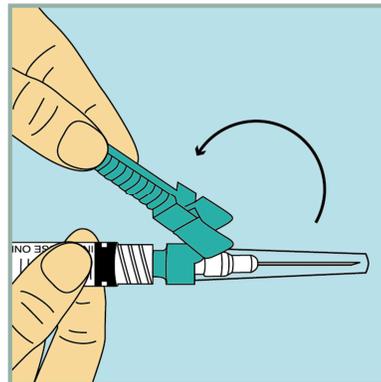
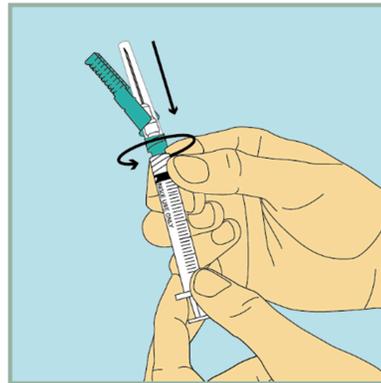


4 Mixing FUZEON

- **Do not** mix FUZEON with tap water. **Use only the sterile water provided to mix FUZEON.**
- **Do not** mix anything or any other medicine in the same syringe as FUZEON.
- **Do not** touch the needle when holding the syringe. If you touch the needle, you will need to start over with a new syringe. If you run out of syringes, call your pharmacy.
- To save time, you can mix both of your daily doses of FUZEON at the same time, but you will need to keep the second vial of mixed FUZEON in the refrigerator. Write the date and time on the vial when mixed if you are mixing the dose to be used later.
- Before using the dose of refrigerated FUZEON, be sure it is clear and allow it to warm to room temperature. You may want to hold it in your hand to help bring it to room temperature before you inject it. **Do not** microwave the vial or put it in hot water.
- **Do not** store mixed FUZEON in the syringe.

Step 5:

- **Draw up the sterile water.**
 - Pick up the 3 mL (large) syringe.
 - Hold the clear plastic cap and tighten the needle with a gentle clockwise twist. **Do not** use too much force as the needle may loosen.
 - Using your index finger, pull the green protection cover away from the capped needle.
 - Pull the clear plastic cap straight off.



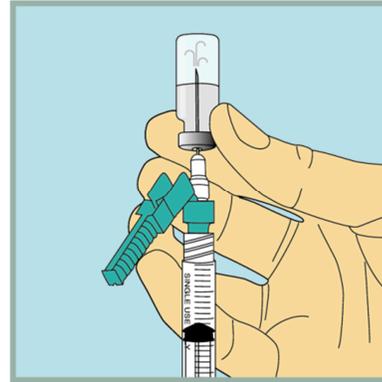
Step 6:

- Slowly pull the plunger back until the tip of the plunger reaches the 1 mL line.



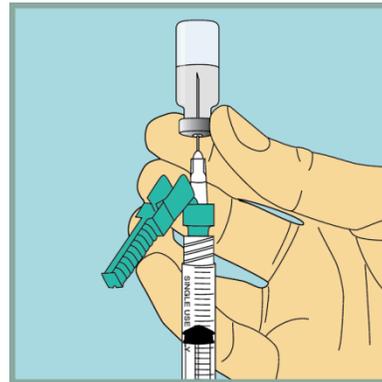
Step 7:

- Push the needle into the rubber stopper of the sterile water vial.
- Turn the vial upside down.
- Slowly push the plunger all the way in to inject the air into the vial. **Do not** remove the needle from the vial.



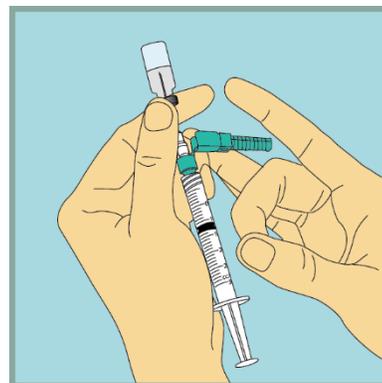
Step 8:

- Make sure the tip of the needle is always below the surface of the sterile water to help keep air bubbles from entering the syringe.
- Slowly pull the plunger back until the tip of the plunger reaches the 1 mL line on the syringe.



Step 9:

- Gently tap or flick the barrel and push and pull the plunger to remove extra air and bubbles. To be sure you end up with 1 mL of sterile water in the syringe, you may need to pull the plunger past the 1 mL line.
- Check to make sure you have 1 mL of sterile water in the syringe. If you have more than 1 mL in the syringe, adjust the amount of sterile water in the syringe by pushing the plunger in until it is 1 mL.
- Carefully remove the needle from the vial.



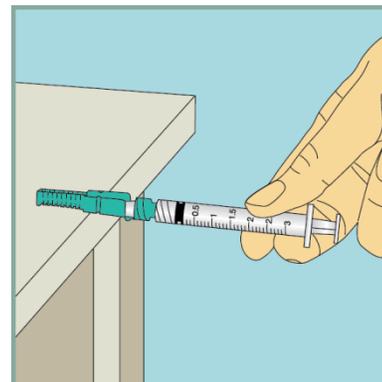
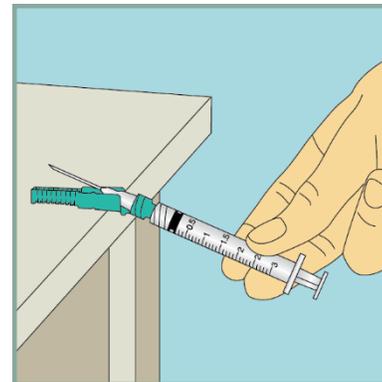
Step 10:

- **Inject sterile water into the FUZEON vial.**
 - Gently tap the FUZEON vial to loosen the powder.
 - Insert the needle of the syringe filled with sterile water into the FUZEON vial at an angle.
 - Point the needle toward the side of the FUZEON vial and **slowly** push the plunger all the way down to inject the sterile water.
 - When injecting the sterile water into the FUZEON vial, the sterile water should drip down the side of the vial into the FUZEON powder.
 - Remove the needle from the vial.



Step 11:

- Using 1 hand, gently press the green protective cover against a flat surface until you hear a click and the needle is re-covered. **Do not use your hand to re-cover the needle.**
- Throw away (dispose of) the used syringe in the sharps container.

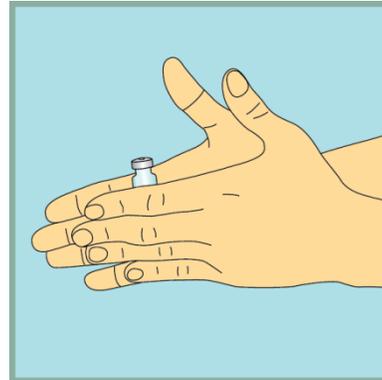




Step 12:

- **Gently mix FUZEON.**

- Gently tap the FUZEON vial with your fingertip for 10 seconds to start dissolving the powder.
- Next, gently roll the FUZEON vial between your hands to reduce the mixing time.
- Once the powder starts to dissolve, just set it aside and it will completely dissolve. **After tapping and gently rolling the FUZEON vial, it could take up to 45 minutes for the FUZEON powder to fully dissolve.**
- **Do not shake the FUZEON vial.** Shaking will make the medicine foam and it will take much longer to dissolve.
- Make sure no FUZEON is stuck to the vial wall.



Step 13:

- **Inspect the FUZEON liquid.**

- **Important:** Completely dissolved and mixed FUZEON should be clear, colorless and without bubbles or particles. If the FUZEON is foamy or jelled, allow more time for it to dissolve.
- If the FUZEON liquid is cloudy, discolored, or you see any particles in it once it is completely mixed and you have waited 45 minutes, **do not** use that vial. Properly throw it away and get a new one.
- If you see bubbles, gently tap the vial until they disappear.



5 Choose and prepare your injection site

- Inject FUZEON exactly as your healthcare provider has shown you.
- Inject FUZEON just under the skin (subcutaneous). FUZEON should **never** be given directly into your veins (intravenous) or directly into your muscle (intramuscular).
- You should change (rotate) your injection site with each injection. **Do not** use the same injection site 2 times in a row.
- Talk with your healthcare provider if you have any questions about where on your body to inject FUZEON.

Step 14:

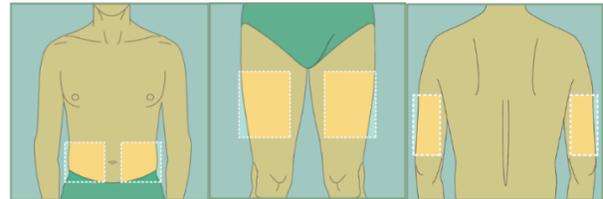
- **Choose your injection site.**

The sites you may choose for your injection are:

- your stomach area (abdomen)
- your upper thigh
- the back of your arm. To inject in the back of your arm, you will need someone to help you.

Do not inject:

- into areas where the skin is tender, bruised, burned or areas with moles, scars or tattoos
- over a blood vessel
- within 2 inches of the belly-button (naval)
- near the elbow, knee, groin, or the lower or inner buttocks



Abdomen

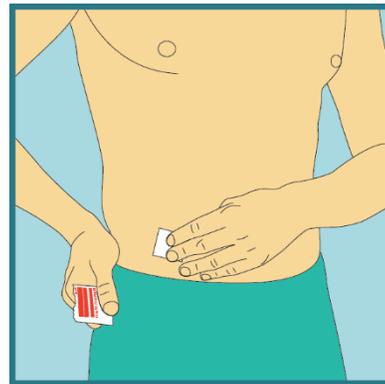
Upper Thighs

Upper Arms

Step 15:

- **Prepare your skin.**

- Clean the injection site with a new sterile alcohol pad. Start in the center, apply pressure and clean in a circular motion, working outward. Allow the site to air-dry. **Do not touch the cleaned area again before injecting.**

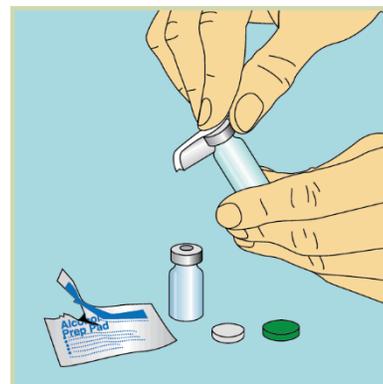


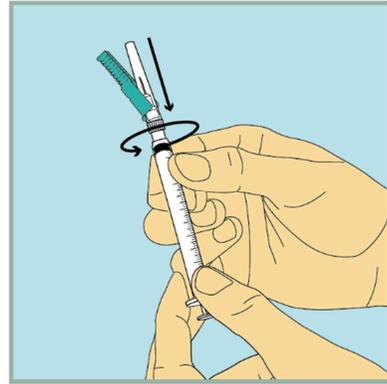
6 Inject FUZEON

Step 16:

- **Draw up your FUZEON dose.**

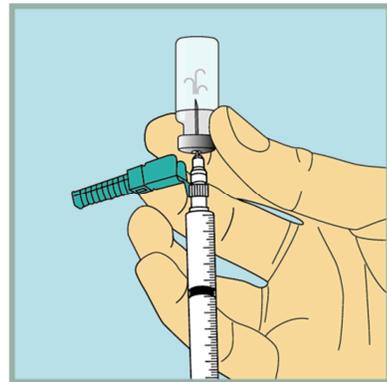
- Clean the FUZEON vial top again, using a new sterile alcohol pad. Allow it to air-dry.
- **Pick up the 1 mL (small) syringe.** Be sure the capped needle is tight by pushing it down slightly while twisting it clockwise.
- Using your index finger, pull the green protective cover away from the capped needle.
- Pull the clear plastic cap straight off.
- Slowly pull back the plunger until the tip of the plunger reaches the 1 mL line.





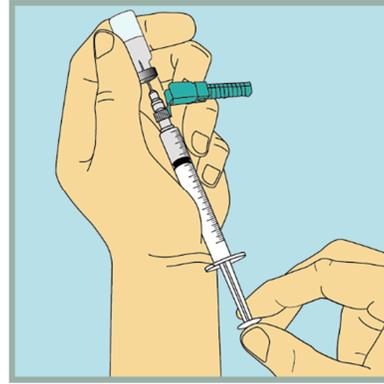
Step 17:

- Insert the needle of the syringe into the vial of mixed FUZEON.
- Gently turn the vial upside down.
- **Slowly** push the plunger all the way down to inject the air into the FUZEON vial. **Do not** remove the needle from the vial.



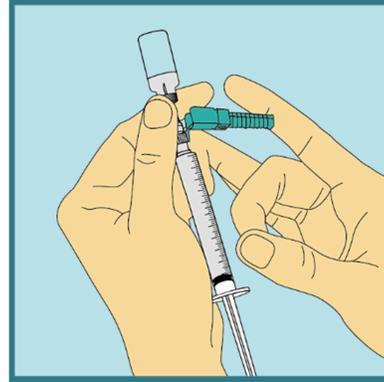
Step 18:

- Make sure the tip of the needle is always below the surface of the FUZEON liquid to help keep air bubbles from entering the syringe.
- **Slowly** pull the plunger down until the tip of the plunger reaches the 1 mL line.



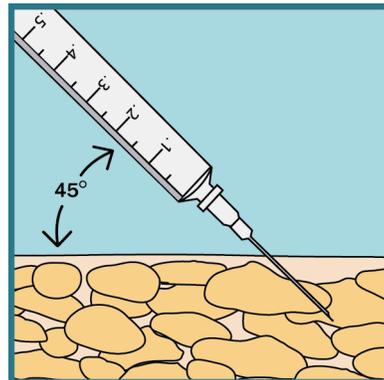
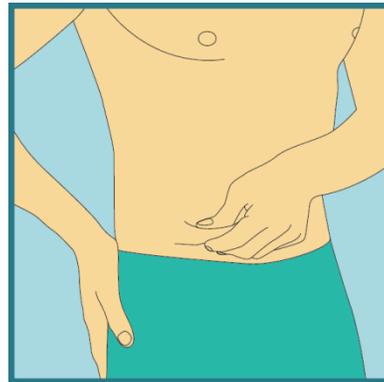
Step 19:

- Gently tap or flick the barrel, and push and pull the plunger to remove extra air and bubbles. To be sure you end up with 1 mL of FUZEON in the syringe, you may need to pull the plunger past the 1mL mark.
- Carefully remove the needle and syringe from the vial.



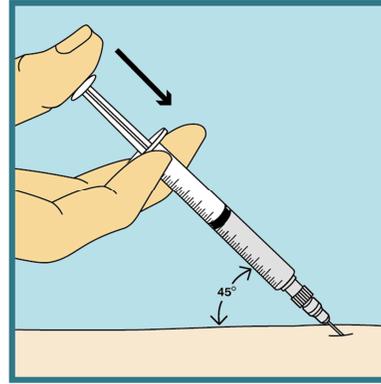
Step 20:

- **Inject your FUZEON dose.**
 - With 1 hand gently pinch and hold a fold of skin around the cleaned injection site.
 - With the other hand, insert the needle into your skin at a 45-degree angle. The needle should be inserted most of the way in. Gently let go of the skin. Make sure the needle stays in place.



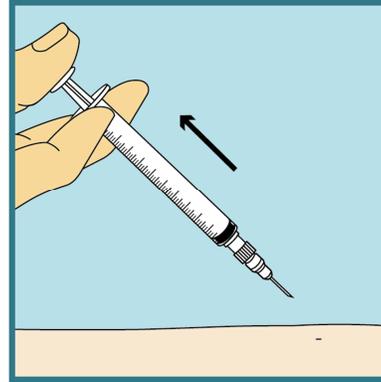
Step 21:

- Slowly push the plunger all the way down until all the FUZEON medicine is injected.



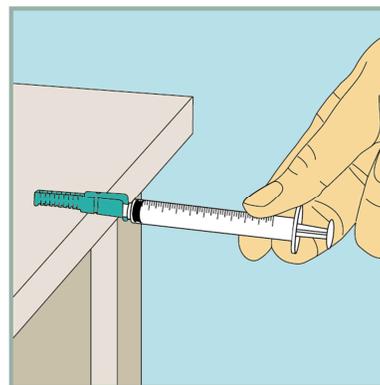
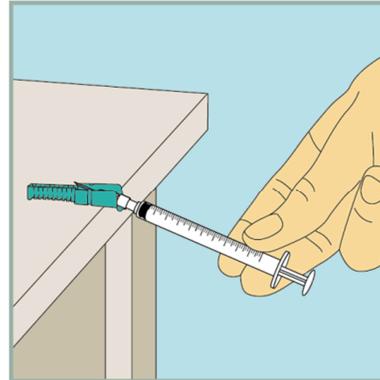
Step 22:

- Remove the needle from your skin.
- Press a dry cotton ball or gauze over the injection site for a few seconds. **Do not** rub the injection site. You may cover the injection site with a small adhesive bandage if needed.



Step 23:

- **After your injection.**
 - Using 1 hand, gently press the colored protective cover of needle against a flat surface until you hear a click and the needle is re-covered. **Do not use your hand to re-cover the needle.**



Dispose of (throw away) your used FUZEON needle and syringe:

- Put your used FUZEON needle and syringe in an FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) your FUZEON needle and syringe 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,
- 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: www.fda.gov/safesharpsdisposal
- **Do not** recycle your used sharps disposal container.

Rx only

FUZEON has been jointly developed by Alexion Pharmaceuticals, Inc. and Hoffmann-La Roche Inc. FUZEON is manufactured by Hoffmann-La Roche Inc.

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1 DNA Way

South San Francisco, CA 94080

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