

Safety Information

What is FUZEON?

FUZEON is a medicine called an HIV (human immunodeficiency virus) fusion inhibitor. FUZEON is always used with other anti-HIV medicines to treat adults and children ages 6 years and older with HIV infection. FUZEON blocks HIV's ability to infect healthy CD4 cells. When used with other anti-HIV medicines, FUZEON can reduce the amount of HIV in the blood and increase the number of CD4 cells. This may keep your immune system healthy, so it can help fight infection.

What are the possible side effects of FUZEON?

Injection site reactions

FUZEON causes injection site reactions. Almost all people get injection site reactions with FUZEON. Reactions are usually mild to moderate, but occasionally may be severe. Reactions on the skin where FUZEON is injected include:

- itching
- swelling
- redness
- pain or tenderness
- hardened skin
- bumps

These reactions generally happen within the first week of FUZEON treatment and usually happen again as you keep using FUZEON. A reaction at one skin injection site usually lasts for less than 7 days. Injection site reactions may be worse when injections are given again in the same place on the body, or when the injection is given deeper than it should be (for example, into the muscle). If you are worried about the reaction you are having, call your healthcare provider to help you decide if you need medical care. **If the injection site reaction you are having is severe, call your healthcare provider right away.** If you have an injection site reaction, you can discuss with your healthcare provider ways to help the symptoms. An injection site can get infected. It is important to follow these FUZEON *Injection Instructions* to lower your chances of getting an injection site infection. Call your healthcare provider right away if there are signs of infection at the injection site such as oozing, increasing heat, swelling, redness or pain.

Pneumonia

Patients with HIV get bacterial pneumonia more often than patients without HIV. In clinical trials, patients taking FUZEON with other HIV medicines got bacterial pneumonia more often than patients not receiving FUZEON. It is unclear if this was related to the use of FUZEON. **You should contact your healthcare provider right away if you have a cough, fever or trouble breathing.** Patients are more likely to get bacterial pneumonia if they had a low number of CD4 cells, increased amount of HIV in the blood, intravenous (injected into the vein) drug use, smoking or had experienced lung disease in the past. It is unclear if pneumonia is related to FUZEON.

Allergic reactions

FUZEON can cause serious allergic reactions. Symptoms of a serious allergic reaction with FUZEON can include:

- trouble breathing
- fever with vomiting and a skin rash
- blood in your urine
- swelling of your feet

Call your healthcare provider right away if you get any of these symptoms.

Other side effects

The following side effects were seen more often in patients using FUZEON with their other anti-HIV medicines than in patients not using FUZEON with their other anti-HIV medicines:

- pain and numbness in feet or legs
- sinus problems
- muscle pain
- loss of sleep
- enlarged lymph nodes
- constipation
- depression
- weight decrease
- pancreas problems
- decreased appetite
- weakness or loss of strength

These are not all the side effects of FUZEON. FUZEON is still being studied in children. The safety of FUZEON in children under 6 years of age is not known. The side effects of FUZEON for HIV-positive children aged 6 through 16 years were the same as seen in adult patients. If you have questions about side effects, ask your healthcare provider. **Report any new or worsening symptoms to your healthcare provider.** Your healthcare provider will tell you what to do and may be able to help you with these side effects.

For more information on FUZEON, please see the patient package insert, www.FUZEON.com and 1-877-4 FUZEON (1-877-438-9366).

Rx only.



Pharmaceuticals



Trimeris, Inc.
3500 Paramount Parkway
Morrisville, North Carolina 27560
www.trimeris.com

Plandex 118144
18-064-118-213-1005

Roche Laboratories Inc.
340 Kingsland Street
Nutley, New Jersey 07110-1199
www.rocheusa.com

Injection Instructions



1 Before You Begin

This is a step-by-step guide to injecting FUZEON® (enfuvirtide) that helps remind you about what you learned at your healthcare provider's office. Complete information about FUZEON is included in the box with your medicine. If you have any questions about using FUZEON, call your healthcare provider or the pharmacy that provided your FUZEON. These instructions are for an adult dose of 1 cc/mL of FUZEON. If your prescription is for less than 1 cc/mL, or if the prescription is for a child, your healthcare provider may tell you to use different syringes.

Safety Tips

- Wash your hands well before starting. Once your hands are clean, **do not** touch anything except the medicine, supplies, and the area around the injection site
- 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, contact your pharmacy
- Do not** touch the tops of the vials once they have been cleaned with an alcohol pad. If you do, clean them again with a new alcohol pad. If you run out of alcohol pads, contact your pharmacy
- Make sure none of the items in your kit have been opened. **Do not** use opened materials
- Never mix FUZEON with tap water. Use only the sterile water provided to mix FUZEON
- Never mix anything or any other medicine in the same syringe as FUZEON
- Inject FUZEON just under the skin (subcutaneous). FUZEON should never be given directly into your veins (intravenous) or directly into your muscle (intramuscular)
- There should never be any particles floating in the FUZEON once it is completely mixed with sterile water. If you see any, **do not** use that vial—contact the pharmacy that provided your FUZEON
- Use syringes, vials of FUZEON and vials of sterile water only one time

Disposing of Used Syringes, Needles, and Supplies

- Put all used syringes and needles directly into the sharps container
- Do not** overfill the sharps container
- Keep the cover on the container and keep it out of the reach of children
- Once the container is full, it is important to safely dispose of it. Never throw the sharps container into the trash. **[1A]** Your healthcare provider or the pharmacy that provided your FUZEON can tell you the right way to dispose of the sharps container
- Used alcohol pads and vials can be thrown into the trash. If you see any blood on an alcohol pad, put it in the sharps container
- If you have any other questions about safely disposing of syringes, needles or supplies, please talk to your healthcare provider or the pharmacy that provided your FUZEON



Having Someone Help You With Injections

Certain injection sites, such as the upper arms, can be hard to use at first. If you need help, ask your partner, a friend or a family member. Anyone who will be helping you should know how to inject FUZEON to lower the chance of getting an accidental needlestick or giving you an infection. They should:

- Meet with your healthcare provider to learn the safe way to give injections
- Read the *Caregiver's Guide to Injecting FUZEON*

2 Injection Sites and Syringe Information

Injection Sites

Changing where you inject FUZEON on your body each time is an important way to lessen how bad your injection site reactions get. For more detailed information about each injection site, see *Your Guide to Taking FUZEON*.



Abdomen



Upper Thighs

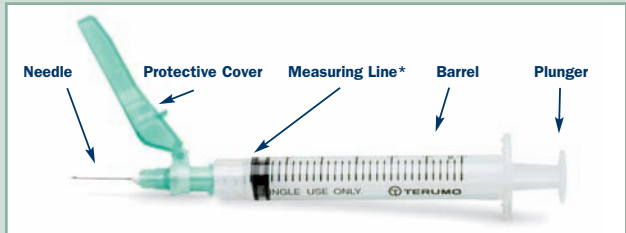


Upper Arms

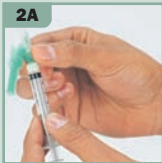
About the Safety Syringe

- There are two different-sized safety syringes, a 3-cc/mL (large) syringe and a 1-cc/mL (small) syringe
- Before using the safety syringe, be sure the clear plastic capped needle is tight by pushing it down gently while twisting it clockwise **[2A]**
- The safety syringes have a colored piece of plastic that is attached to the needle. This piece of plastic is a safety feature that covers the needle after use, lowering the risk of needlestick injuries **[2B, 2C]**
- Your healthcare provider may recommend other types of syringes for use with FUZEON
- Never throw your used syringes into the trash. Put them in the sharps container

Parts of the Syringe:



* The measuring line of the syringe is the edge line of the plunger closest to the needle. Terumo is a registered trademark of Terumo Medical Corporation.



3 Getting Started

Gather Supplies

Gather the following supplies for each dose and put them on your FUZEON Preparation Mat or a cleaned surface: **[3A]**

- One vial of FUZEON—at room temperature
- One vial of sterile water
- One 3-cc/mL (large) syringe with a 1-inch needle
- One 1-cc/mL (small) syringe with a 1/2-inch needle
- Alcohol pads
- Sharps container



Prepare Supplies

- Open the syringe packages and take the caps off the vials
- Throw the syringe packages and vial caps into the trash

Wash Hands

- Wash your hands well using soap and warm water and dry them with a clean towel **[3B]**
- Once your hands are clean, **do not** touch anything other than the medicine, supplies and the area around the injection site



Clean Vial Tops

- Wipe each vial top with a new alcohol pad and let the tops air-dry **[3C]**
- If you touch the rubber tops after cleaning them, clean them again with a new alcohol pad

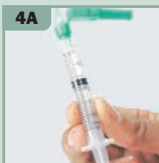
Mixing Two Doses

- 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. **Do not** store mixed FUZEON in the syringe
- Once sterile water has been added to the FUZEON, the vial can be placed in the refrigerator. The FUZEON will dissolve in time for your next dose
- 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
- Mixed FUZEON must be used within 24 hours
- The instructions below are for mixing a single dose. If you want to mix two doses at the same time, be sure to use new alcohol pads, syringes, medicine and sterile water
- Write the date and time on the vial when mixed if you are mixing the dose to be used later

4 Mixing FUZEON

Draw Up Sterile Water

- Gently tap the FUZEON vial to loosen the powder
- Pick up the 3-cc/mL (large) syringe
- Using your index finger, pull the colored protection device away from the capped needle
- To ensure that the needle is secure, 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 **[2A]**
- Pull the clear plastic cap off
- Pull the plunger back to get 1.1 cc/mL of air **[4A]**
- Before turning the sterile water vial upside down, *slowly* inject the air into the vial—and keep the needle in the vial
- Turn the vial upside down. Make sure the tip of the needle is always below the surface of the water to help keep air bubbles from entering the syringe **[4B]**
- *Slowly* pull the plunger back to get 1.1 cc/mL of sterile water into the syringe
- **Tip!** 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 1.1 cc/mL of sterile water in the syringe, you may need to pull the plunger past the 1.1 cc/mL mark. **[4C]**
- Carefully remove the needle and syringe from the vial



- Remove the needle from the vial. Using one hand, gently press the colored protective cover against a flat surface until you hear a click and the needle is re-covered. *Never use your hand to re-cover the needle* **[2B, 2C]**
- Put the used syringe in the sharps container **[4E]**



Gently Mix FUZEON

- Gently tap the FUZEON vial with your fingertip for 10 seconds to start dissolving the powder. Then gently roll the FUZEON vial between your hands to reduce the mixing time. **[4F]** Make sure no FUZEON is stuck to the vial wall. After tapping, it could take up to 45 minutes to dissolve
- **Important!** Never shake the FUZEON vial. Shaking will make the medicine foam and it will take much longer to dissolve.
- Once the powder starts to dissolve, just set it aside and it will completely dissolve



Inspect FUZEON

- When completely mixed, the liquid FUZEON should be clear
- **Important!** Completely dissolved FUZEON should be clear and without foam. **[4G]** If the FUZEON is foamy **[4H]** or jelled, allow more time for it to dissolve.
- If you see bubbles, gently tap the vial until they disappear
- If you see any particles in the FUZEON once it is completely mixed, **do not** use that vial. Contact the pharmacy that provided it
- Mixed FUZEON must be used right away or stored in the vial in the refrigerator and used within 24 hours. **Do not** store mixed FUZEON in the syringe



Inject Sterile Water Into FUZEON

- Insert the syringe with sterile water into the FUZEON vial at an angle
- Inject the sterile water *slowly*, so that it drips down the side of the vial into the FUZEON powder **[4D]**

5 Giving the Injection

Choose the Injection Site

- Using your FUZEON *Planner* to help you, choose a site **different** from the one you used for your last injection
- **Important!** With the tips of your fingers, feel for any hard bumps. **Do not** inject in or near bumps or any other types of reactions from past injections. Also, **do not** inject into moles, scars, bruises, your belly button or areas that could be irritated by a belt or waistband. **[5A]**
- Clean the injection site with a new alcohol pad. Start in the center, apply pressure and clean in a circular motion, working outward. Allow the site to air-dry **[5B]**



Draw Up FUZEON

- Clean the FUZEON vial top again, using a new alcohol pad. Allow it to air-dry
- Pick up the 1-cc/mL (small) syringe
- **Important!** Be sure the capped needle is tight by pushing it down slightly while twisting it clockwise. **[2A]**
- Using your index finger, pull the colored needle-protection device away from the capped needle
- Pull the clear plastic cap off
- Pull back the plunger to get 1 cc/mL of air
- Insert the syringe into the vial of mixed FUZEON
- Before turning the vial upside down, *slowly* inject the air into the FUZEON, and keep the needle in the vial
- Gently turn the vial upside down **[5C]**



- Make sure the tip of the needle is always below the surface of the FUZEON to help keep air bubbles from entering the syringe. *Slowly* pull the plunger to get 1 cc/mL of FUZEON **[5D]**
- **Tip!** 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 cc/mL of FUZEON in the syringe, you may need to pull the plunger past the 1 cc/mL mark. **[5E]**
- Carefully remove the needle and syringe from the vial



Inject FUZEON

- Pinch and hold a fold of skin around the injection site **[5F]**
- Pierce the skin at a 45-degree angle. The needle should be inserted most of the way in **[5G]**
- **Tip!** Your healthcare provider may teach you to inject in a different way.
- Slowly push the plunger all the way to inject FUZEON
- Remove the needle from your skin
- Using one hand, gently press the colored protective cover against a flat surface until you hear a click and the needle is re-covered. *Never use your hand to re-cover the needle* **[2B, 2C]**
- Put the used syringe in the sharps container **[5H]**
- Cover the site with a small bandage if you see any blood or medicine

