

Information for Patients and Caregivers (New as of November 2006)



FUZEON (few'-zee-on)

Generic Name: enfuvirtide (en-few'-ver-tide) for Injection

R_x only

WHAT IS FUZEON?

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DOES FUZEON LOWER THE CHANCE OF PASSING HIV TO OTHER PEOPLE?

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CHANGES SINCE THE LAST VERSION OF THIS LEAFLET

This leaflet contains important information for patients and their caregivers about FUZEON. Please read this leaflet and *FUZEON Injection Instructions* carefully before you start using FUZEON. Always read the section “*Changes since the last version of this leaflet*” at the end of this leaflet each time you get your FUZEON prescription refilled. There may be new important information about the use of FUZEON.

This information does not take the place of talking with your healthcare provider about your medical conditions or treatment.

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.

Does FUZEON cure HIV and AIDS?

FUZEON does not cure HIV infection or AIDS. People taking FUZEON may still get opportunistic infections or other conditions that can happen with HIV infection. **For these reasons it is very important that you remain under the care of your healthcare provider while taking FUZEON.**

Does FUZEON lower the chance of passing HIV to other people?

FUZEON does not lower your chance of passing HIV to other people through unprotected sex, sharing needles or being exposed to your blood. For your own health and the health of others, it is important to continue to practice safer sex. Use a latex or polyurethane condom or other barrier method to lower the chance of sexual contact with semen, vaginal secretions or blood. Never use dirty needles or share needles. Ask your healthcare provider if you have any questions about safer sex or how to prevent passing HIV to other people.

Who should not use FUZEON?

Do not use FUZEON if you are allergic to any of the ingredients in FUZEON. See the end of this leaflet for a list of ingredients in FUZEON.

Tell your healthcare provider:

- **if you are pregnant or plan to become pregnant.** We do not know if FUZEON can harm your unborn child. You and your healthcare provider will need to decide if FUZEON is right for you. If you use FUZEON while you are pregnant, talk to your healthcare provider about how you can be in the Antiretroviral Pregnancy Registry.
- **if you are breast-feeding.** You should not breast-feed if you are HIV-positive because of the chance of passing the HIV virus to your baby. Also, it is not known if FUZEON can pass into your breast milk and if it can harm your baby.
- **about all your medical conditions.**
- **about all the medicines you use,** including prescription and non-prescription medicines, vitamins, and herbal supplements. FUZEON has not been tested with all medicines.

FUZEON does not affect other anti-HIV medicines or the medicine rifampin (also known as rifampicin, Rifadin[®] or Rimactane[®]). You can take FUZEON at the same times or at different times than your other anti-HIV medicines.

How should I use FUZEON?

Before you use FUZEON, make sure you understand all of the information in this leaflet and the FUZEON *Injection Instructions* that come with your medicine. You or your caregiver should be trained by a healthcare provider before injecting it. If you do not

understand all the information or are having a hard time mixing or injecting FUZEON, talk with your healthcare provider.

- Use FUZEON with other anti-HIV medicines. You can take FUZEON at the same time or at a different time than your other anti-HIV medicines.
- **Do not use FUZEON as your only anti-HIV medicine.**
- FUZEON must be injected. FUZEON does not work if the medicine is swallowed.
- Do not mix other medicines in the same syringe with FUZEON.
- FUZEON is given under the skin by injection (a “shot”) in the upper arm, upper leg or stomach two times a day. See the FUZEON *Injection Instructions* that come with your medicine for step-by-step instructions about how to inject FUZEON.
- Do not inject FUZEON in the same area as you did the time before. Do not inject FUZEON into the following areas: near the elbow, knee, groin, the lower or inner buttocks, directly over a blood vessel, around the navel (belly button), scar tissue, a bruise, a mole, a surgical scar, tattoo or burn site, or where there is an injection site reaction.
- If the FUZEON is foamy or jelled, allow more time for it to dissolve. Do not inject FUZEON if you see particles floating in the FUZEON vial after you mix it up.
- You can use FUZEON whether you have eaten or not. Food does not affect FUZEON. However, you must keep taking your other medicines the way you did before.
- Do not change your dose or stop taking FUZEON without first talking with your healthcare provider.
- See your healthcare provider regularly while using FUZEON.
- When your FUZEON supply runs low, be sure to have it refilled. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. If you miss or skip doses of FUZEON, HIV may develop resistance to FUZEON and become harder to treat.
- If you miss a dose of FUZEON, take the missed dose as soon as you can and then take your next dose as scheduled. If you have missed a dose of FUZEON and it is close to the time when you are supposed to take your next dose, wait and take the next dose as regularly scheduled. Do not take two doses of FUZEON at the same time.
- If you take too much FUZEON, call your healthcare provider right away. We do not know what can happen if you take too much FUZEON. You will be watched very carefully if you take too much FUZEON.
- **It is important that you put your used syringes into a special sharps container after injecting FUZEON.** Your healthcare provider will give you more instructions

about the safe disposal of your used syringes. **Do not put them in a trash can.** If you do not have a sharps container, call your healthcare provider or pharmacist to get one before using FUZEON.

What should I avoid while using FUZEON?

- Avoid doing anything that can spread HIV infection since FUZEON does not stop you from passing the HIV infection to others.
- Do not share needles or other injection equipment.
- Do not share personal items that can have blood or body fluids on them, like toothbrushes or razor blades.
- Do not have any kind of sex without protection. Always practice safer sex by using a latex or polyurethane condom or other barrier method to reduce the chance of sexual contact with semen, vaginal secretions or blood.
- Do not drive or operate heavy machinery if FUZEON makes you feel dizzy.

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 the FUZEON *Injection Instructions* that come with your medicine 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.**

Injection using Biojector® 2000

Shooting nerve pain and tingling lasting up to 6 months from injecting close to large nerves or near joints, and bruising and/or collections of blood under the skin have been reported with use of the Biojector 2000 needle-free device to inject FUZEON. If you are taking any blood thinners, or have hemophilia or any other bleeding disorder, you may be at higher risk of bruising or bleeding after using the Biojector.

Pneumonia

Patients with HIV get bacterial pneumonia more often than patients without HIV. Patients taking FUZEON with other HIV medicines may get bacterial pneumonia more often than patients not receiving FUZEON. It is unclear if this is 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
- loss of sleep
- depression
- decreased appetite
- sinus problems
- enlarged lymph nodes
- weight decrease
- weakness or loss of strength
- muscle pain
- constipation

- pancreas problems

These are not all the side effects of FUZEON. For more information, ask your healthcare provider or pharmacist.

If you have questions about side effects, ask your healthcare provider. **Report any new or continuing 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.

How is FUZEON stored?

FUZEON vials not mixed with sterile water can be stored at room temperature (59° to 86°F). FUZEON should be refrigerated if it cannot be stored at room temperature.

The Sterile Water for Injection (diluent) may be stored at room temperature (59° to 86°F).

After FUZEON has been mixed with the sterile water, the vial can be stored in a refrigerator for up to 24 hours.

Do not use FUZEON or sterile water after the expiration date on the vials. Do not keep FUZEON that is out of date or that you no longer need.

If you have more questions about how to store FUZEON, ask your healthcare provider or pharmacist or call 1-877-4FUZEON.

General information about the safe and effective use of FUZEON

Medicines are sometimes prescribed for conditions not mentioned in patient information leaflets. Do not use FUZEON for a condition for which it was not prescribed. Do not give FUZEON to other people, even if they have the same symptoms you have. It may harm them. **Keep FUZEON and all medicines out of the reach of children.**

This leaflet summarizes the most important information about FUZEON. If you would like more information, talk with your healthcare provider or see the section, “*Where can I get more information about FUZEON?*” in this leaflet. You can ask your healthcare provider or pharmacist for information about FUZEON that is written for health professionals.

What are the ingredients in FUZEON?

Active Ingredient: enfuvirtide

Inactive Ingredients: Mannitol, sodium carbonate, sodium hydroxide, and hydrochloric acid.

FUZEON comes packaged as a Convenience Kit containing the following:

- 60 vials of FUZEON
- 60 vials of Sterile Water for Injection (2 cartons of 30 each)
- syringes for mixing (3 cc)
- syringes for injecting (1 cc)
- alcohol pads

Call your healthcare provider or pharmacist if you need more supplies.

Where can I get more information about FUZEON?

The best source for more information about FUZEON is your healthcare provider. More information about FUZEON can be found at www.FUZEON.com and 1-877-4FUZEON (1-877-438-9366).


Changes since the last version of this leaflet

Clarification of appropriate injection sites for FUZEON and addition of side effects when injecting with Biojector 2000 needle-free device.

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