

Patient Information
FUZEON® (few'-zee-on)
(enfuvirtide) Injection

What is FUZEON?

FUZEON is a prescription medicine used in combination with other antiretroviral medicines to treat Human Immunodeficiency Virus-1 (HIV-1) infection in people who have taken other antiretroviral medicines and whose HIV-1 levels have continued to increase while on treatment.

HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).

It is not known if FUZEON is safe and effective for use in children under 6 years of age.

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

Before using FUZEON, tell your healthcare provider about all your medical conditions, including if you:

- have bleeding problems
- have or had lung problems
- have a low CD4 count
- smoke or use intravenous (IV) street drugs
- are pregnant or plan to become pregnant. It is not known if FUZEON can harm your unborn baby. Tell your healthcare provider if you become pregnant during treatment with FUZEON.
 - **Pregnancy Registry:** There is a pregnancy registry for women who use antiretroviral medicines during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry.
- are breastfeeding or plan to breastfeed. **Do not breastfeed if you use FUZEON.**
 - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
 - It is not known if FUZEON passes into your breast milk.
 - Talk to your healthcare provider about the best way to feed your baby during treatment with FUZEON.

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

Especially tell your healthcare provider if you take medicines that affect blood clotting.

Some medicines interact with FUZEON. Keep a list of your medicines to show to your healthcare provider and pharmacist when you get a new medicine.

You can ask your healthcare provider or pharmacist for a list of medicines that interact with FUZEON.

Do not start a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to use FUZEON with other medicines.

How should I use FUZEON?

- Read the FUZEON "Injection Instructions" for information about how to prepare and inject FUZEON.
- Use FUZEON exactly as your healthcare provider tells you to.
- **Do not** stop using FUZEON or change your dose without first talking with your healthcare provider.
- **Your healthcare provider should show you how to prepare and inject FUZEON before you inject it for the first time.** Do not use FUZEON until you have been shown how to inject FUZEON the right way.
- FUZEON is injected under the skin (subcutaneously) of your stomach (abdomen), outer thigh, or upper arm.
- Change (rotate) your injection site with each injection. **Do not** use the same site for each injection.
- **Do not** inject FUZEON into areas with scars, moles, bruises, tattoos, burns, blood vessels, or in the area within 2 inches of your belly button (naval).
- **FUZEON must be used in combination with other antiretroviral medicines.** Do not use FUZEON as your only antiretroviral medicine.
- See your healthcare provider regularly while using FUZEON.
- If you take too much FUZEON, call your healthcare provider right away.

What should I avoid while using FUZEON?

- Do not drive, operate heavy machinery, or do other dangerous activities until you know how FUZEON affects you.

What are the possible side effects of FUZEON?

FUZEON may cause serious side effects, including:

- **Injection site reactions.** Injection site reactions including pain and discomfort, redness, rash, itching and bruising have happened in people who use FUZEON. Call your healthcare provider right away if you have pain, redness, or swelling around the injection site that does not go away within a few days or gets worse.
- **Nerve pain (neuralgia) or numbness, burning, or prickling feeling of your skin (paresthesia)** have happened in people who use the Biojector 2000 needle-free device to give their FUZEON dose. These symptoms can last up to 6 months.
- **Bleeding after your injection.** People who take medicines that affect blood clotting (anticoagulants) or people with hemophilia or other blood clotting problems may have a higher risk.
- **Allergic reactions.** Stop using FUZEON and call your healthcare provider or go to the nearest hospital emergency room right away if you develop any of these signs and symptoms of an allergic reaction:
 - rash
 - fever
 - chills
 - trouble breathing
 - hives
 - nausea and vomiting
 - swelling of your face, eyes, lips or mouth
 - low blood pressure
- **Pneumonia.** Pneumonia which can be serious and cause hospitalization and death has happened in people who use FUZEON. Call your healthcare provider or go to the nearest hospital emergency room right away if you develop any of these signs or symptoms of pneumonia:
 - cough with fever
 - fast breathing
 - shortness of breath
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when an HIV-1 infected person starts taking antiretroviral medicines including FUZEON. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you start having any new symptoms after starting FUZEON.

The most common side effects of FUZEON include:

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| ○ local injection site reactions | ○ stomach pain | ○ pneumonia |
| ○ diarrhea | ○ cough | ○ pain and numbness in feet or legs |
| ○ nausea | ○ herpes simplex | ○ flu-like symptoms |
| ○ tiredness | ○ decreased appetite | ○ infected hair follicle |
| ○ weight loss | ○ pancreas problems | ○ dry mouth |
| ○ sinus problems | ○ pain in arms and legs | ○ eye infection |

These are not all the possible side effects of FUZEON.

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 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 48°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.

General information about the safe and effective use of FUZEON.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. 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. 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

Distributed by:

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

More information go to www.FUZEON.com or call 1-877-438-9366.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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