

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



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4 **FUZEON® (few'-zee-on)**

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

6 **R<sub>x</sub> only**

7 WHAT IS FUZEON?

8 DOES FUZEON CURE HIV AND AIDS?

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

10 WHO SHOULD NOT USE FUZEON?

11 **HOW SHOULD I USE FUZEON?**

12 WHAT SHOULD I AVOID WHILE USING FUZEON?

13 **WHAT ARE THE POSSIBLE SIDE EFFECTS OF FUZEON?**

14 HOW IS FUZEON STORED?

15 GENERAL INFORMATION ABOUT THE SAFE AND EFFECTIVE USE OF  
16 FUZEON

17 WHAT ARE THE INGREDIENTS IN FUZEON?

18 WHERE CAN I GET MORE INFORMATION ABOUT FUZEON?

19 CHANGES SINCE THE LAST VERSION OF THIS LEAFLET

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

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

27 **What is FUZEON?**

28 FUZEON is a medicine called an HIV (human immunodeficiency virus) fusion inhibitor.  
29 FUZEON is always used with other anti-HIV medicines to treat adults and children ages  
30 6 years and older with HIV infection.

31 FUZEON blocks HIV’s ability to infect healthy CD4 cells. When used with other anti-  
32 HIV medicines, FUZEON can reduce the amount of HIV in the blood and increase the

33 number of CD4 cells. This may keep your immune system healthy, so it can help fight  
34 infection.

35 **Does FUZEON cure HIV and AIDS?**

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

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

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

48 **Who should not use FUZEON?**

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

51 **Tell your healthcare provider:**

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

63 FUZEON does not affect other anti-HIV medicines or the medicine rifampin (also  
64 known as rifampicin, Rifadin<sup>®</sup> or Rimactane<sup>®</sup>). You can take FUZEON at the same  
65 times or at different times than your other anti-HIV medicines.

66 **How should I use FUZEON?**

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

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

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

### 110 **What should I avoid while using FUZEON?**

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

### 120 **What are the possible side effects of FUZEON?**

121 Injection site reactions

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

- 125 • itching
- 126 • swelling
- 127 • redness
- 128 • pain or tenderness
- 129 • hardened skin
- 130 • bumps

131

132 These reactions generally happen within the first week of FUZEON treatment and usually  
133 happen again as you keep using FUZEON. A reaction at one skin injection site usually  
134 lasts for less than 7 days.

135 Injection site reactions may be worse when injections are given again in the same place  
136 on the body or when the injection is given deeper than it should be (for example, into the  
137 muscle).

138 If you are worried about the reaction you are having, call your healthcare provider to help  
139 you decide if you need medical care. **If the injection site reaction you are having is**  
140 **severe, call your healthcare provider right away.** If you have an injection site reaction,  
141 you can discuss with your healthcare provider ways to help the symptoms.

142 An injection site can get infected. It is important to follow the FUZEON *Injection*  
143 *Instructions* that come with your medicine to lower your chances of getting an injection

144 site infection. **Call your healthcare provider right away if there are signs of infection**  
145 **at the injection site such as oozing, increasing heat, swelling, redness or pain.**

#### 146 **Injection using Biojector® 2000**

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

#### 152 **Pneumonia**

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

#### 161 **Allergic reactions**

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

- 164 • trouble breathing
- 165 • fever with vomiting and a skin rash
- 166 • blood in your urine
- 167 • swelling of your feet

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

#### 169 **Other side effects**

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

- 173 • pain and numbness in feet or legs
- 174 • loss of sleep
- 175 • depression
- 176 • decreased appetite
- 177 • sinus problems
- 178 • enlarged lymph nodes
- 179 • weight decrease
- 180 • weakness or loss of strength
- 181 • muscle pain
- 182 • constipation

183 • pancreas problems

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

186 If you have questions about side effects, ask your healthcare provider. **Report any new**  
187 **or continuing symptoms to your healthcare provider.** Your healthcare provider will  
188 tell you what to do and may be able to help you with these side effects.

### 189 **How is FUZEON stored?**

190 FUZEON vials not mixed with sterile water can be stored at room temperature (59° to  
191 86°F). FUZEON should be refrigerated if it cannot be stored at room temperature.

192 The Sterile Water for Injection (diluent) may be stored at room temperature (59° to  
193 86°F).

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

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

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

### 200 **General information about the safe and effective use of FUZEON**

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

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

### 210 **What are the ingredients in FUZEON?**

211 Active Ingredient: enfuvirtide

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

214 FUZEON comes packaged as a Convenience Kit containing the following:

- 215 • 60 vials of FUZEON
- 216 • 60 vials of Sterile Water for Injection (2 cartons of 30 each)
- 217 • syringes for mixing (3 cc)
- 218 • syringes for injecting (1 cc)
- 219 • alcohol pads

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

221 **Where can I get more information about FUZEON?**

222 The best source for more information about FUZEON is your healthcare provider. More  
223 information about FUZEON can be found at [www.FUZEON.com](http://www.FUZEON.com) and 1-877-4FUZEON  
224 (1-877-438-9366).

225 **Changes since the last version of this leaflet**

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

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229 Rifadin is a trademark of Merrell Pharmaceuticals Inc.

230 Rimactane is a trademark of Ciba.

231 Biojector is a trademark of Bioject Medical Technologies, Inc.

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233 FUZEON is manufactured by Hoffmann-La Roche Inc.

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