

1 **Information for Patients and Caregivers (New as of December 2005)**



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4 **FUZEON<sup>®</sup> (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: around the navel (belly button), scar tissue, a  
82 bruise or a mole, and where there is an injection site reaction.
  - 83 • If the FUZEON is foamy or jelled, allow more time for it to dissolve. Do not inject  
84 FUZEON if you see particles floating in the FUZEON vial after you mix it up.
  - 85 • You can use FUZEON whether you have eaten or not. Food does not affect  
86 FUZEON. However, you must keep taking your other medicines the way you did  
87 before.
  - 88 • Do not change your dose or stop taking FUZEON without first talking with your  
89 healthcare provider.
  - 90 • See your healthcare provider regularly while using FUZEON.
  - 91 • When your FUZEON supply runs low, be sure to have it refilled. This is very  
92 important because the amount of virus in your blood may increase if the medicine is  
93 stopped for even a short time. If you miss or skip doses of FUZEON, HIV may  
94 develop resistance to FUZEON and become harder to treat.
  - 95 • If you miss a dose of FUZEON, take the missed dose as soon as you can and then  
96 take your next dose as scheduled. If you have missed a dose of FUZEON and it is  
97 close to the time when you are supposed to take your next dose, wait and take the  
98 next dose as regularly scheduled. Do not take two doses of FUZEON at the same  
99 time.
  - 100 • If you take too much FUZEON, call your healthcare provider right away. We do not  
101 know what can happen if you take too much FUZEON. You will be watched very  
102 carefully if you take too much FUZEON.
  - 103 • **It is important that you put your used syringes into a special sharps container**  
104 **after injecting FUZEON.** Your healthcare provider will give you more instructions  
105 about the safe disposal of your used syringes. **Do not put them in a trash can.** If you

106 do not have a sharps container, call your healthcare provider or pharmacist to get one  
107 before using FUZEON.

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

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

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

119 Injection site reactions

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

- 123 • itching
- 124 • swelling
- 125 • redness
- 126 • pain or tenderness
- 127 • hardened skin
- 128 • bumps

129

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

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

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

140 An injection site can get infected. It is important to follow the FUZEON *Injection*  
141 *Instructions* that come with your medicine to lower your chances of getting an injection  
142 site infection. **Call your healthcare provider right away if there are signs of infection**  
143 **at the injection site such as oozing, increasing heat, swelling, redness or pain.**

144 **Pneumonia**

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

153 **Allergic reactions**

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

- 156 • trouble breathing
- 157 • fever with vomiting and a skin rash
- 158 • blood in your urine
- 159 • swelling of your feet

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

161 **Other side effects**

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

- 165 • pain and numbness in feet or legs
- 166 • loss of sleep
- 167 • depression
- 168 • decreased appetite
- 169 • sinus problems
- 170 • enlarged lymph nodes
- 171 • weight decrease
- 172 • weakness or loss of strength
- 173 • muscle pain
- 174 • constipation
- 175 • pancreas problems

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

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

181 **How is FUZEON stored?**

182 FUZEON vials not mixed with sterile water can be stored at room temperature (59° to  
183 86°F). FUZEON should be refrigerated if it cannot be stored at room temperature.

184 The Sterile Water for Injection (diluent) may be stored at room temperature (59° to  
185 86°F).

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

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

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

192 **General information about the safe and effective use of FUZEON**

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

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

202 **What are the ingredients in FUZEON?**

203 Active Ingredient: enfuvirtide

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

206 FUZEON comes packaged as a convenience kit containing the following:

- 207 • 60 vials of FUZEON  
208 • 60 vials of Sterile Water for Injection (2 cartons of 30 each)  
209 • syringes for mixing (3 cc)  
210 • syringes for injecting (1 cc)  
211 • alcohol pads

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

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

214 The best source for more information about FUZEON is your healthcare provider. More  
215 information about FUZEON can be found at [www.FUZEON.com](http://www.FUZEON.com) and 1-877-4 FUZEON  
216 (1-877-438-9366).

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219 Rimactane is a trademark of Ciba.  
  
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