

# Fuzeon (enfuvirtide)



*Fuzeon is a white or off-white powder that must be reconstituted with sterile water before injecting under the skin. Vials of Fuzeon come in a "kit" with bottles of sterile water and syringes.*



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**Also known as:** T-20 and pentafuside.

**Background.** Fuzeon is an anti-HIV drug manufactured by Trimeris, Inc. and distributed by Roche Pharmaceuticals. The drug blocks entry of HIV into cells by inhibiting fusion of the virus and the cell. Fuzeon must be taken with other anti-HIV drugs, and has shown particular effectiveness when used with a protease inhibitor boosted with Norvir as part of the HIV regimen. The FDA approved Fuzeon in March 2003.

**Dose.** The recommended dose of Fuzeon is 1 mg of reconstituted drug twice a day, injected under the skin into the upper arm, anterior thigh, or abdomen.

**Food restrictions.** Fuzeon may be taken with or without food.

**Directions for use.** Fuzeon must be mixed with 1.1 mL of sterile water prior to injection. Once the water has been added to the drug, the vial should be gently tapped for 10 seconds and then gently rolled between the hands to avoid foaming. The vial should be allowed to stand until the powder is completely dissolved, which can take up to 45 minutes. The vial should be inspected to ensure that all the powder is dissolved and the liquid is clear and colorless. If particles remain, the vial must not be used and should be returned to the pharmacy.

**Storage.** Fuzeon should be stored at room temperature (77°F). Once reconstituted, Fuzeon may be stored in the refrigerator, but it must be used within 24 hours. If refrigerated, Fuzeon must be brought back to room temperature before injection.

**Patient assistance.** A patient assistance program for reimbursement counseling can be reached at 866.694.6670. This telephone number is for doctors, patients, and their advocates.

**Side effects and toxicity.** Fuzeon can cause itching, swelling, redness, pain, tenderness, hardened skin, and bumps at sites where it is injected.

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Almost all persons who use Fuzeon get some type of reaction at the site of injection. These reactions can be mild to moderate and occasionally may be severe. Injecting at the same place in the body or too deeply (for example, into the muscle) may result in worse reactions. Also, injection sites may get infected.

Patients should watch for symptoms of pneumonia such as cough with fever, rapid breathing, and shortness of breath. Though not common in clinical trials, patients taking Fuzeon tended to get pneumonia more frequently than those not taking Fuzeon.

A few patients in the Fuzeon trials had a hypersensitivity reaction to the drug. The symptoms of hypersensitivity included rash, fever, nausea, vomiting, chills, rigidity or shakes, low blood pressure, and elevated liver enzymes (for example, serum liver transaminases). Patients with any or all of these symptoms are advised to stop taking Fuzeon and consult with their doctor. Peripheral neuropathy, anxiety, lymphadenopathy, and suicide ideation were added to the list of *other reported AEs*. Peripheral neuropathy, anxiety and lymphadenopathy were common, but mild.

**Drug interactions.** Because Fuzeon is not metabolized by the liver, it is not known to have any significant drug interactions.

**Obtaining Fuzeon.** Until further notice, prescriptions for Fuzeon will be filled on a first-come, first served basis by a single pharmacy: Chronimed/StatScript. To learn more about the process for filing prescriptions your healthcare provider can call 866.694.6670 or go to the website [www.fuzeon.com](http://www.fuzeon.com) to get more information and a "Prescription Enrollment Form." Fuzeon comes with an syringes, but alternative syringes can be used: talk with your healthcare provider. Also, the company is currently looking at a new way to inject Fuzeon directly into the skin as a quickly discharged mist using a "Biojector" device.

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## Additional info:

**Resistance and cross resistance.** Virus with resistance to Fuzeon selected *in vitro* shows mutations in the HR1 domain at positions 36 to 38 of the HIV-1 envelope glycoprotein gp41. Phenotypic analysis of these *in vitro* selected mutations show a 5-fold to 648-fold decreased susceptibility to Fuzeon. *In vivo*, the virus selects for mutations in gp41 amino acid positions 36 to 45 with decreased drug susceptibility ranging from 4-fold to 422-fold.

**Clinical data.** Approval of Fuzeon was based on 2 randomized, controlled, open-label, multicenter trials in heavily treatment-experienced HIV-1-infected subjects. The trials are named T20-301 and T20-302. More commonly they are referred to as TORO-1 and TORO-2 (**T**-20 vs. **O**ptimized **R**egimen **O**nly). In these trials participants were required to have either (1) viremia despite 3 to 6 months prior therapy with a nucleoside reverse transcriptase inhibitor (NRTI), non-nucleoside reverse transcriptase inhibitor (NNRTI), and protease inhibitor (PI) or (2) viremia and documented resistance or intolerance to at least 1 member in each of the NRTI, NNRTI, and PI classes.

Trial participants received genotypic and phenotypic resistance tests. A background regimen consisting of 3 to 5 anti-HIV drugs was selected on the basis of the results of the resistance tests. Subjects were randomized 2:1 to receive Fuzeon + background regimen versus background regimen alone.

On the basis of the pooled data from both TORO studies, the following results were obtained. The participants in the Fuzeon + background regimen had a viral load drop from baseline of 1.52 log<sub>10</sub> copies/mL as compared to the participants on background regimen alone who experienced only a drop of only 0.73 log<sub>10</sub> copies/mL from baseline. Participants with 2 or more active drugs in their background regimen were more likely to achieve a viral load of less than 400 copies/mL. In addition, subjects on the Fuzeon + background regimen had a CD4+ T cell count increase of 71 cells/mm<sup>3</sup> at 24 weeks, as compared to the subjects on background regimen alone who had a CD4+ T cell count increase of only 35 cells/mm<sup>3</sup> at 24 weeks.

Subjects on the Fuzeon + background regimen were more likely to achieve viral loads of less than 400 copies/mL (52% versus 26%) and more likely to achieve viral loads of less than 50 copies/mL (23% versus 9%).



To contact The Center for AIDS,  
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