Enfuvirtide *(Fuzeon)*

Drug Summary

Enfuvirtide (also known as T-20), is the only FDA-approved HIV fusion inhibitor. Enfuvirtide is a potent antiretroviral agent that must be delivered by twice-daily subcutaneous injections. Approval of enfuvirtide by the FDA was based on studies in heavily treatment-experienced individuals, in which enfuvirtide was added to an optimized background regimen. Use of enfuvirtide frequently results in painful injection site reactions, such as subcutaneous nodules and irritation. Because these reactions limit enfuvirtide tolerability, the use of enfuvirtide is generally limited to salvage therapy for patients with extensive treatment history, multiclass antiretroviral resistance, and few antiretroviral therapy options. The need for enfuvirtide decreased dramatically following the approval of multiple potent antiretroviral agents that have activity in the setting of common HIV resistance-associated mutations. In the current era, the use of enfuvirtide is limited but could include treatment of a person with severe multi-drug resistant HIV or as a component of a temporary antiretroviral regimen in a person unable to take any oral medications, such as after abdominal surgery.

Key Clinical Trials

[TORO 1]: The phase 3 TORO-1 study was a multi-center international study enrolled adults with virologic failure (HIV RNA greater than 5,000 copies/mL) who had at least 6 months of previous treatment with agents in three classes (NRTI, NNRTI, and PI) of antiretroviral drugs and/or resistance to drugs in these three classes of drugs.[1] A total of 501 participants were randomized 2:1 ratio to receive enfuvirtide plus an optimized background regimen of three to five antiretroviral drugs or such a regimen alone (control group). At week 24, individuals in the enfuvirtide arm had a 1.7 log reduction in HIV RNA levels, compared to 0.8 log reduction in the control group. At week 24, virologic failure had occurred in 16.0% in the enfuvirtide group and in 33.3% of the control group. Injection site reactions were very common in persons receiving enfuvirtide.

[TORO-2]: The phase 3 TORO-2 study was a multi-center study conducted in Europe and Australia adults that enrolled 521 with virologic failure (HIV RNA greater than 5,000 copies/mL) who had at least 3 months of
previous treatment with agents in three classes (NRTI, NNRTI, and PI) of antiretroviral drugs and/or resistance
to drugs in these three classes of drugs.[2] A total of 501 participants were randomized 2:1 ratio to receive
enfuvirtide plus an optimized background regimen of three to five antiretroviral drugs or such a regimen
alone (control group). At week 24, individuals in the enfuvirtide arm had a 1.4 log reduction in HIV RNA levels,
compared to 0.6 log reduction in the control group. At week 24, virologic failure had occurred in 19.1% in the
enfuvirtide group and in 40.2% of the control group. Injection site reactions were very common in persons
receiving enfuvirtide.

Manufacturer for United States

Enfuvirtide (Fuzeon [few'-zee-on]) is available as in a single-dose lyophilized powder for injection containing
108 mg enfuvirtide per vial to provide delivery of 90 mg for injection (Figure 1). Enfuvirtide (Fuzeon) is
manufactured by Genentech.

Key Drug Interactions

For complete information on enfuvirtide-related drug interactions, see the Drug Interactions section in the
Enfuvirtide (Fuzeon) Prescribing Information.

Citations


Figures

Figure 1. Enfuvirtide (Fuzeon) Vial