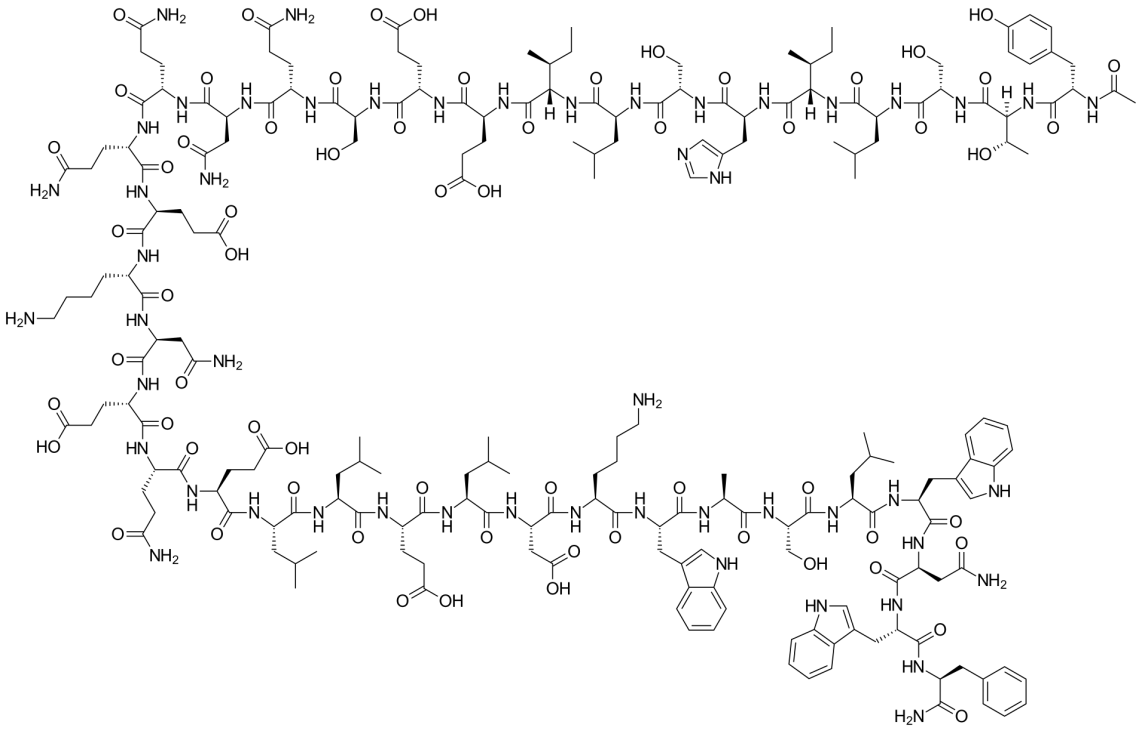
**Brand Name:** Fuzeon
**Generic:** enfuvirtide
**Type:** monoclonal antibody
**Year Accepted/Phase:** 2003

## Mechanism:

Enfuvirtide is a fusion inhibitor that blocks the HIV-1 virus from entering human CD4 cells. It binds to the gp41 subunit of the viral envelope glycoprotein, preventing the conformational changes necessary for the fusion of the viral and cellular membranes, stopping the virus from entering and infecting the cells.

## Chemical Structure:



## Indication:

Fuzeon is indicated for the treatment of HIV-1 infection in combination with other antiretroviral agents in treatment-experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy.

## Clinical trials:

### TORO 1 Trial (Phase III)

**Pubmed:** https://pubmed.ncbi.nlm.nih.gov/12637625/
**Purpose:** Evaluate the efficacy and safety of enfuvirtide in combination with an optimized background regimen (OBR) compared to OBR alone in treatment-experienced patients with HIV-1.
**Dates:** Results published in 2003.
**Results:** Patients receiving enfuvirtide in combination with OBR showed a significant reduction in viral load and an increase in CD4 cell counts compared to those receiving OBR alone. The median reduction in viral load was significantly greater in the enfuvirtide group.
**Impact:** These results demonstrated the potential of enfuvirtide as an effective treatment option for patients with multidrug-resistant HIV.

### TORO 2 Trial (Phase III)

**Pubmed:** https://pubmed.ncbi.nlm.nih.gov/12637625/
**Purpose:** Further evaluate the efficacy and safety of enfuvirtide in a similar patient population as TORO 1, but in different geographic regions.
**Dates:** Results published in 2003.
**Results:** Consistent with TORO 1, the TORO 2 trial showed that enfuvirtide in combination with OBR significantly reduced viral load and increased CD4 cell counts compared to OBR alone. The results from TORO 2 reinforced the findings from TORO 1.
**Impact:** The positive outcomes from both TORO trials led to the FDA approval of Fuzeon in March 2003.

### Long-Term Follow-Up Studies

**Purpose:** Assess the long-term safety and efficacy of enfuvirtide in treatment-experienced HIV-1 patients.
**Dates:** Various studies with follow-up results published between 2004 and 2008.
**Results:** Long-term use of enfuvirtide was associated with sustained virologic suppression and immunologic improvement in many patients. However, the injectable nature of the drug and injection site reactions were noted as significant considerations in long-term use.