



ENFUVRTIDE

GENERAL INFORMATION

- Therapeutic class: Fusion inhibitor.
- WHO guidelines: Not currently included in WHO guidelines. Indicated for treatment-experienced adult patients who have evidence of viral HIV-1 replication despite ongoing antiretroviral therapy.¹⁴¹
- Originator company and product brand name: Roche and Trimeris, Fuzeon.
- First approval by U.S. Food and Drug Administration (FDA): March 2003.²³
- WHO Model List of Essential Medicines (EML): Not included in the 17th edition.²⁴
- World sales of originator product: There are no sales figures listed in the companies' annual report.
- Patents: The basic patent on enfuvirtide was applied for by Duke University in June 1994,¹⁴² and is due to expire in 2014. Duke researchers founded the pharmaceutical company Trimeris,

which began development of enfuvirtide (previously called T-20) in 1996. In 1999, Trimeris entered into partnership with Hoffmann-La Roche to complete the development of the drug. Chiron also owns patents related to processes for producing enfuvirtide,¹⁴³ which expired in 2005, but protection has been extended until 2010 in some European countries. A licensing agreement was established between Roche and Chiron in 2004.¹⁴⁴

PRICE INFORMATION

Roche was invited to contribute a price for this publication and communicated that it does not offer a lower price for developing countries and is not planning to offer one in the future.

SPOTLIGHT ON ACCESS ISSUES

Enfuvirtide is the first drug developed in the fusion inhibitor class, whose novel mechanism of action prevents the penetration of target cells by the HIV virus. This new drug is predominately used in the developed world as 'salvage therapy' for patients who are already resistant to multiple antiretroviral agents.

Enfuvirtide is formulated as an injection and requires the patient or caregiver to learn how to reconstitute powder vials with sterile water. Since the vials are formulated for single use, the patient or caregiver needs to accurately syringe out the required dose and volume. This makes the drug ill-adapted for use in resource-limited settings.

There is no generic version of this drug yet available and Roche offers no reduced pricing for the developing world. The current price in some developed countries of nearly \$28,000 per patient per year is prohibitive for many developing countries that may have a need for this product.¹⁴⁵

Patents

In developing countries such as China and Brazil, Trimeris filed for patents related to methods for synthesizing enfuvirtide, which may run until 2019.¹⁴⁶

The patent was granted in China.³⁸

In Brazil, enfuvirtide is available at \$12,812 ppy.¹⁴⁷

Paediatrics

Enfuvirtide is approved for use in children over six years of age.¹⁴⁸ To simplify treatment for all children, there is an urgent need for studies on enfuvirtide to be completed in infants and children under six, and for child-adapted formulations to be made available.