European Medicines Agency

EMEA/H/C/514

EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

FUZEON

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Fuzeon?

Fuzeon is a powder that is made up into a solution for injection. It contains the active substance enfuvirtide (90 mg/ml).

What is Fuzeon used for?

Fuzeon is an antiviral medicine. It is used in combination with other antiviral medicines for the treatment of patients infected with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS). It is for use in patients who have stopped responding to, or cannot take, other antiviral medicines. These must include at least one medicine from each of the following classes of medicine used to treat HIV infection: protease inhibitors; non-nucleoside reverse transcriptase inhibitors; and nucleoside reverse transcriptase inhibitors.
Doctors should only prescribe Fuzeon once they have looked at the antiviral medicines the patient has taken before and the likelihood that the virus will respond to the medicine.
The medicine can only be obtained with a prescription.

How is Fuzeon used?

Fuzeon should be prescribed by a doctor who has experience in the treatment of HIV infection. In adults, it is given as one 90-mg injection twice a day, injected under the skin of the upper arm, upper thigh or abdomen (tummy). The dose for children aged six to 16 years depends on body weight. Fuzeon is not recommended for use in children under six years of age.
Fuzeon can be injected by the patient or by a carer, provided that the person giving the injection follows the detailed instructions given in the Package Leaflet. The site of injection must be changed for each injection.

How does Fuzeon work?

The active substance in Fuzeon, enfuvirtide, is a fusion inhibitor. Fuzeon binds to a protein on the surface of HIV. This prevents the virus from attaching to the surface of human cells and infecting them. As HIV can only reproduce itself within cells, Fuzeon, taken in combination with other antiviral medicines, reduces the level of HIV in the blood and keeps it at a low level. Fuzeon does not cure HIV infection or AIDS, but it may delay the damage to the immune system and the development of infections and diseases associated with AIDS.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 16
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

How has Fuzeon been studied?
The two main studies of Fuzeon included 1,013 patients aged 16 years or over who were infected with HIV and had taken, or were not responding to, other antiviral medicines. On average, the patients had been given an average of 12 antiviral medicines over a seven-year period. Both studies compared the effects of Fuzeon, in combination with 'optimised background therapy' (a combination of other antiviral medicines chosen for each patient as they had the best chances of reducing the levels of HIV in the blood), compared with optimised background therapy without Fuzeon. The main measure of effectiveness was the change in the levels of HIV in the blood (viral load) after 48 weeks of treatment. Fuzeon has also been studied in 39 children aged between three and 16 years. The studies were still ongoing at the time of the medicine's assessment.

What benefit has Fuzeon shown during the studies?
Taking Fuzeon with optimised background therapy was more effective at reducing viral loads than optimised background therapy alone. In the first study, viral loads fell by an average of 98% in the patients taking Fuzeon, compared with 83% in the patients not taking Fuzeon. The values in the second study were 96 and 78%, respectively. The approved dose of Fuzeon in children brings about similar levels of the active substance in the blood to the approved dose in adults.

What is the risk associated with Fuzeon?
The most common side effects with Fuzeon (seen in more than 1 patient in 10) are injection site reactions (pain and inflammation at the site of injection), peripheral neuropathy (damage to the nerves in the extremities causing tingling or numbness in the hands and feet) and weight loss. In clinical studies, injection site reactions have been reported in 98% of patients, mostly occurring within the first week of treatment. It caused mild to moderate pain or discomfort, which did not increase during treatment. For the full list of all side effects reported with Fuzeon, see the Package Leaflet.
Fuzeon should not be used in people who may be hypersensitive (allergic) to enfuvirtide or any of the other ingredients.
As with all other anti-HIV medicines, patients taking Fuzeon may be at risk of osteonecrosis (death of bone tissue) or immune reactivation syndrome (symptoms of infection caused by the recovering immune system). Patients who have problems with their liver may be at an elevated risk of liver damage when taking treatment for HIV infection.

Why has Fuzeon been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that Fuzeon's benefits are greater than its risks in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected patients who have received treatment with and failed on regimens containing at least one medicinal product from each of the following classes, protease inhibitors, non-nucleoside reverse transcriptase inhibitors and nucleoside reverse transcriptase inhibitors, or who have intolerance to previous antiretroviral regimens. The Committee recommended that Fuzeon be given marketing authorisation.
Fuzeon was originally authorised under 'Exceptional Circumstances', because for scientific reasons it had not been possible to obtain complete information on the medicine. As the company had supplied the additional information requested, the 'Exceptional Circumstances' ended on 8 July 2008. 2008.

Other information about Fuzeon:
The European Commission granted a marketing authorisation valid throughout the European Union for Fuzeon to Roche Registration Limited on 27 May 2003. The marketing authorisation was renewed on 27 May 2008.

The full EPAR for Fuzeon can be found here.

This summary was last updated in 07-2008.