



ENFUVIRTIDE (Fuzeon)

WHAT IS ENFUVIRTIDE?

Enfuvirtide, also called Fuzeon or T-20, is a drug used for antiviral therapy. It is manufactured by Roche and Trimeris.

Enfuvirtide is the first "fusion inhibitor" drug. When HIV infects a cell, it attaches to the outside of the cell. Then it "fuses" or joins itself with the cell. Enfuvirtide stops this process of fusion. This means that HIV cannot infect that cell.

WHO SHOULD TAKE IT?

Enfuvirtide was approved in 2003 as an antiviral drug against HIV. It was studied in adults and in children over 6 months of age. There are no absolute rules about when to start antiviral drugs. You and your doctor should consider your CD4 cell count, your viral load, any symptoms you are having, and your attitude about taking HIV medications. Fact Sheet 404 has more information about guidelines for the use of antiviral medications.

Enfuvirtide is injected twice a day. It will most likely be used by people who have very few choices of antiviral medications in pill form.

If you take enfuvirtide with other antiviral drugs, you can reduce your viral load and increase your CD4 cell counts. This should mean staying healthier longer.

WHAT ABOUT DRUG RESISTANCE?

The HIV virus is sloppy when it makes copies of its genetic code (RNA). Many new copies of HIV are mutations: they are slightly different from the original virus. Some mutations can continue to multiply even when you are taking an antiviral drug. When this happens, the drug will stop working. This is called "developing resistance" to the drug. See Fact Sheet 126 for more information on resistance.

Resistance to enfuvirtide can develop quickly if it is taken by itself. With combination therapy (taking more than one antiviral drug at the same time), HIV mutates much more slowly. Resistance takes longer to develop. **It is very**

important to take antiviral medications according to instructions, on schedule, and not to skip or reduce doses. Recent research showed that enfuvirtide can be effective even when HIV appears to have some resistance to it.

Sometimes, if you develop resistance to one drug, you will also have resistance to other antiviral drugs. This is called "cross-resistance". Enfuvirtide does not have cross resistance with any other antiviral drugs.

HOW IS ENFUVIRTIDE TAKEN?

If enfuvirtide is swallowed, it is destroyed by stomach acids. This means that it cannot be taken in pill form. Enfuvirtide is injected just under the skin. This is called a "subcutaneous" injection.

The adult dosage of enfuvirtide is 90 mg per injection, twice a day. The dosage for children is based on their body weight. Once-daily injections of enfuvirtide are being studied.

If your doctor prescribes enfuvirtide, you will shown how to prepare each injection, and how and where to inject it. It can take about 40 minutes to prepare a dose of enfuvirtide. You can prepare both of a day's doses at the same time. Avoid injecting near large nerves (ask your health care provider). Also, don't inject where you have had a reaction from a previous injection or into moles, tattoos, scar tissue, bruises, or your navel.

A new injector (the Biojector) was considered for use with enfuvirtide. However, in October 2007 Roche stopped trying to get it approved.

Enfuvirtide is a new class of antiviral drug. This means that it is active against HIV that has developed resistance to any other antiviral drug. However, it cannot be used by itself. It must be combined with other antiviral drugs.

WHAT ARE THE SIDE EFFECTS?

The most common side effects of enfuvirtide are skin reactions where the drug is injected. Almost everybody who uses enfuvirtide gets these reactions. They can be very mild, such as slight redness. They can include itching, swelling, pain, hardened skin, or hard lumps. Each reaction might last up to a week.

With two injections each day, people using enfuvirtide might have reactions at several spots on their body at the same time. Very few patients have stopped using it because of skin reactions.

The most common other side effects of enfuvirtide are headache, pain and numbness in feet or legs, dizziness, and loss of sleep. People taking enfuvirtide seem to have a higher rate of bacterial pneumonia. Be sure your health care provider knows about any lung problems you are having.

HOW DOES IT REACT WITH OTHER DRUGS?

Enfuvirtide has been studied to see if it interacts with other drugs. There are no known interactions with other anti-HIV medications. However, it has not been studied with all medicines, over-the-counter drugs or vitamin or herbal supplements. Be sure your doctor knows about all medications and supplements that you are taking.

THE BOTTOM LINE

Enfuvirtide is the first drug in a new class. It stops HIV from "fusing" with a cell it has attached to. This prevents HIV from infecting the cell. Enfuvirtide helps control HIV, even when it is resistant to other medications.

Enfuvirtide has to be injected under the skin twice daily. Almost everyone who uses it gets skin reactions where it is injected. Most of these are not serious.

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