

T-20 (enfuvirtide, Fuzeon)

Summary

T-20 is a type of anti-HIV drug called a fusion inhibitor. It is currently used only in people who have developed resistance to many other anti-HIV drugs. T-20 is taken at a dose of 90 mg twice daily, which must be given by injection under the skin. Common side effects are related to the injections and include temporary itching, swelling, pain or tenderness, and bumps at the sites where it is injected.

What is T-20?

T-20, sold under the brand name Fuzeon, is a type of anti-HIV (antiretroviral) drug called a fusion inhibitor. T-20 is used in combination with other anti-HIV drugs to treat (but not cure) HIV.

How does T-20 work?

T-20 is the first drug in a relatively new class of anti-HIV drugs called fusion inhibitors. Fusion inhibitors like T-20 stop HIV from attaching (fusing) to the outside of the cell, preventing it from getting inside the cell at all.

T-20 is a very large molecule compared to other anti-HIV drugs. If taken orally (in pill form), the digestive system would break it down into pieces that would no longer work. Therefore, it has to be delivered directly into the blood to be effective. (Other anti-HIV drugs can be taken orally because the digestive system leaves their smaller molecules intact.)

How do people with HIV use T-20?

T-20 is used in combination with other anti-HIV drugs from different classes. Such combinations are called antiretroviral therapy, or ART. For more information on ART, see CATIE's *Your Guide to HIV Treatment*.

FACT SHEET

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T-20 is approved for use in treatment-experienced HIV-positive adults who are resistant to other anti-HIV drugs. (See “Drug Resistance” below). Neither T-20 nor any other anti-HIV medication is a cure for HIV. It is therefore important that you do the following:

- See your doctor regularly so that he/she monitors your health.
- Continue to practice safer sex and take other precautions so as not to pass HIV on to other people and to protect yourself from infection with other strains of HIV and other germs.

Warnings

1. Lung infections

Infections in the lungs occurred more frequently in people who were taking T-20 in clinical trials (3.6%, compared to 0.6% of the control group). This included bacterial pneumonia as well as other kinds of pneumonia. About half of the people who developed pneumonia needed to be hospitalized. Several of these people died; however, all of the deaths were in people who also had other serious, unrelated illnesses.

2. Hypersensitivity reactions

Fewer than 1% of people taking T-20 have had hypersensitivity reactions—a type of severe allergic reaction that can cause rash, fever, chills, nausea and vomiting, and/or lowered blood pressure. People who suspect a hypersensitivity reaction to T-20 should stop taking the drug and get immediate medical attention. T-20 should not be restarted if a hypersensitivity reaction is confirmed.

Side effects

1. Injection site reactions

In clinical trials, the majority of T-20 users (up to 98%) reported injection site reactions (ISRs)—symptoms at the spot where the dose was injected. These symptoms include pain and discomfort,

hardened skin, redness, bumps, itching and swelling. Only about 4% of people have had to stop taking T-20 because of ISRs. The reactions usually fade within a week. T-20 is injected at a different spot each time to allow the ISRs time to fade.

2. Other side effects

Other side effects that have been reported by some T-20 users include lymphadenopathy (swollen lymph nodes)

In clinical trials, diarrhea, nausea and vomiting, headaches and fatigue have been seen *less* frequently in people taking T-20 with other anti-HIV drugs, compared to people taking other anti-HIV drugs without T-20.

Drug interactions

Always consult your doctor and pharmacist about taking any other prescription or non-prescription medication, including herbs, supplements, and street drugs.

Some drugs can interact with T-20, increasing or decreasing its levels in your body. Increased drug levels can cause you to experience side effects or make pre-existing side effects worse. On the other hand, if drug levels become too low, HIV can develop resistance and your future treatment options may be reduced.

It may also be necessary to avoid drugs that do not affect other drug levels, but cause similar side effects.

If you must take a drug that has the potential to interact with your existing medications, your doctor can do the following:

- adjust your dose of either your anti-HIV drugs or other medications
- prescribe different anti-HIV drugs for you

Drug interactions with T-20

The following drugs interact or have the potential to interact with T-20. This list is not exhaustive.

- T-20 appears to increase levels of the protease inhibitor tipranavir (Aptivus). This has not led to an increase in side effects in clinical trials. However, there has been one report of severe liver toxicity in one person with HIV using tipranavir who later added T-20 to his regimen. Levels of liver enzymes rose to several times above normal levels. This person was also co-infected with hepatitis B.

No other significant drug interactions have been seen in any of the large clinical trials of T-20; it is generally considered unlikely to interact significantly with other drugs.

Resistance and cross-resistance

Over time, as new copies of HIV are made in the body, the virus changes its structure. These changes are called mutations and can cause HIV to resist the effects of anti-HIV drugs, which means those drugs will no longer work for you. Extensive resistance mutations can make it challenging for “highly pre-treated” people (those who have been on many previous treatments from different drug classes) to find an effective drug combination.

T-20 can be an option for many treatment-experienced people with HIV, because they have not been exposed to fusion inhibitors and have therefore not developed resistance to this drug class. Many people have been able to suppress their viral load below the 50-copy mark by starting a new treatment regimen containing T-20 and an “optimal” combination of other anti-HIV drugs that is chosen for best possible effect.

To maximize the chances of treatment success and to delay the development of drug resistance:

- T-20 should be combined with as many other active anti-HIV drugs as possible.
- Resistance testing and expert consultation should be used to identify the best other medications.

- All of the new drugs should be started together, rather than adding T-20 to an existing combination.

To reduce the risk of developing drug resistance, all anti-HIV drugs should be taken every day exactly as prescribed and directed. If doses are delayed, missed, or not taken as prescribed, levels of T-20 in the blood may fall too low. If this happens, resistant virus can develop. If you find you are having problems taking your medications as directed, speak to your doctor and nurse about this. They can find ways to help you.

Dosage and formulations

The standard adult dose of T-20 is 90 mg injected under the skin twice a day.

T-20 is dispensed in single-use sterile vials, each containing enfuvirtide in powdered form. Each dose must be prepared for use by injecting sterile water (supplied along with the drug) into the vial, shaking and leaving it to stand. This produces a reconstituted solution containing 90 mg/mL of enfuvirtide, of which a one mL (90 mg) dose is then injected. Both of a day’s doses can be prepared at once; the reconstituted solution can be kept refrigerated for up to 24 hours.

Formulations can change, and dosages may need to be customized. All medications should always be taken as prescribed and directed.

Availability

T-20 is licensed in Canada for the treatment of HIV infection in adults whose previous therapy has failed. T-20 must be taken in combination with other anti-HIV drugs. Your doctor can tell you more about the availability and coverage of T-20 in your region. CATIE’s online module *Federal, Provincial and Territorial Drug Access Programs* also contains information about Canadian drug coverage.

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