

## T-20: ISRs and other side effects

Associated drugs: T-20 (enfuvirtide, Fuzeon)

T-20 is the first drug in a new class of HIV drugs called entry inhibitors.

The main advantages of T-20 are:

- that it is active against HIV that is resistant to any of the other classes of drugs
- that it is an 'entry inhibitor'. This means that it works on HIV before CD4 cells are infected. Nukes, PIs and NNRTIs work on cells that are infected by HIV. Side effects associated with some nukes, PIs and NNRTIs, such as mitochondrial toxicity and lipodystrophy, are unlikely to be caused by entry inhibitors.

The main disadvantages are that:

- T-20 has to be used in combination with other active drugs. Otherwise the benefit is only temporary and resistance develops
- It is not an oral drug. T-20 is given by sub-cutaneous injection (under the skin, not into a vein or muscle).

Because the benefits are significant and life saving for people with both resistance to existing drugs, and who have a low CD4 count, and because of the more complicated way that the drug is given, we have taken several pages to cover T-20 in detail.

Comments and suggestions for this section were provided by people who already use T-20 successfully in their combination.

### ISRs - Injection site reactions

Nearly everyone who uses T-20 gets some level of skin reaction where the T-20 is injected but some people report no problems at all. Less than 5% of people discontinue treatment for this reason.

These reactions can include soreness and redness; nodules, bumps or cysts; and itching or other irritation. ISRs commonly last for a week or less in 75% people.

Often these symptoms are mild and manageable, and they may be minimised by good injection practice described below

The severity of the reactions is difficult to predict, and can vary in the same person. Some people follow all the best advice and are still unlucky and get erratic reactions. Sometimes this may be due to factors that you can't control.

The information in this guide only provides a limited overview on how to reduce the risk of these reactions.

The manufacturer (Roche) has developed extensive support material that everyone receiving T-20 is given. You will be given this detailed information, together with training before you use T-20.

This pack includes:

- detailed printed information
- 1-2-1 training from nurses (or from your hospital)
- a training video (if appropriate)
- phone numbers of patients already on treatment

## Preparation and reconstitution

T-20 needs to be given twice a day.

Although one study looked at giving both doses at the same time once a day, this was not as effective as twice daily. In some people, drug levels at the end of the 24 hour period were too low, and this increased the risk of the treatment failing, and getting resistance to T-20.

However, each day both doses T-20 can be mixed up at the same time. It is very safe to mix both doses in the morning, for example, and leave the evening dose in the fridge until you come to use it later.

- Set aside an hour for preparation, especially when starting out, so that you are not rushed or hurried.
- Wash your hands before starting the preparation and don't touch anything other than the preparation materials during this process.
- Don't touch the needles or the tops of the vials after they have been cleaned with alcohol swabs.
- Prepare a clear space that is not cluttered with anything else. Use the preparation mat to lay out all the equipment.
- Lay out all the materials before you start and make sure that nothing is already opened or used.
- Only use the sterile water to reconstitute T-20. Never use tap water or other water.

- Always use the exact quantities recommended. Take your time when drawing up water into the syringe. Inject the water slowly into the T-20 vial at an angle. It should drip down the side of the vial into the powder.
- Gently tap the vial to start the T-20 dissolving. Then set it to one side to let it slowly finish dissolving completely. This may take up to 45 minutes.
- Don't shake the vial as this will cause the mixture to foam and it will take longer to settle down before you can inject it.

When the T-20 is fully dissolved, the liquid should be clear. There should not be any powder left on the sides of the vial. If there is, you should not use this vial.

There should also not be any air bubbles or foam. If there is, then the vial needs more time to settle.

Once mixed, the reconstituted T-20 should be used straight away, or put into the fridge for use in the evening. Reconstituted T-20 that is kept in the fridge needs to be used within 24 hours.

Detailed information on how to use the syringes is provided in the training pack given to every patient. Different syringes have been used, including fine diabetic needles, and these may change again in the future. This is why we have not included information on specific syringes in this guide.

## Choice of injection sites

T-20 is injected under the skin so you need to pick an area that has most tissue or fat. Do not inject into muscle, and never inject into a vein.

Recommended injection sites are:

- Thighs - the top of legs
- Abdomen - your stomach, but not near your belly button
- Upper arms and back
- Buttocks are not generally recommended unless you have no other options and your doctor or nurse agrees to try this.

Changing where you inject T-20 each day is important.

- Do not inject into an area that is still swollen or inflamed from an earlier injection. Feel for any earlier bumps under the skin so that you can avoid these.
- Do not inject into moles, scars, bruises, not the area around your belly button or any area of skin that will be rubbed - ie by a belt.
- If you are prone to ISRs, wearing loose clothing can help
- You may want to ask a friend to help you with injections, especially in some of the more difficult to inject sites like the upper arms.

This person should also receive training, including precautions if they accidentally prick themselves with a needle after giving you an injection.

Because T-20 is injected under the skin, and not into a vein, it is very unlikely to be a risk for HIV transmission.

- Some people report that having a warm bath first helps to soften the skin and make the injection process easier.

Clean the area to inject with an alcohol swab and allow to air-dry.

Pinch the area of skin that will be injected. Make sure the skin is dry and the cleaning alcohol has evaporated.

- Make sure that no T-20 touches the surface of the skin and that it is only injected once the needle is under the skin. Both these things will limit any burning sensation.

Then insert the needle at a 45-degree angle with the flat angled edge facing up, and inject the T-20 very slowly.

Several posts to the FuzeonSupport email discussion group have included varying the angle up to 90 degrees. It may be that you have to experiment to see if one method is better for you.

A half-inch needle should go all the way in to the hub.

The injection needs to be under the skin and not so deep that it reaches muscle. If you have very little body fat then choosing the area with the most fat is recommended.

After injecting, put all the used syringes and needles into the sharps container.

This should be kept away from children and collected by your clinic when it is full.

Never throw needles into general rubbish bins.

## Massage and ice packs

Gently massaging the injection site after giving the injection may help reduce the risk of injection site reactions. This can be using your hands, with or without non-irritating oils, or using an electrical massager.

It will also help distribute the drug more quickly and more evenly. The nodules that sometimes occur have T-20 in those tissues, although the inflammatory reaction is unlikely to be related to the local concentration of T-20.

Some people find that an ice pack afterwards can help reduce the swelling. Some people use a warm hot-water bottle. You will have to experiment to see whether or not these options help you.

Creams such as a mild hydrocortisone or benedryl cream may help with more severe reactions.

## Getting used to needles

Most people report that they get used to using needles very quickly. But it may seem strange at first. Try to focus on the benefit you are getting against HIV. For example, contact lenses are strange when you use them for the first time and this may be a bit similar.

Carrying needles, travelling and leading a normal life

Many people are able to fit using T-20 into a normal and active life. If you travel you can always find a quiet space to inject if you need too. One person took their first dose of T-20 in an aeroplane on their way to Moscow.

Take a letter with you from your doctor, that says you need the syringes for

medical treatment, and that you are fit and healthy to travel.

The injection process may sound strange when you first have to think about it. Talking to someone already using T-20 may help and your hospital can arrange this.

## Needle free injections

Over the last few years some patients in the US were able to use a new system to inject T-20.

Instead of needles, the 'Bioject' system uses pressurised gas to inject T-20 through the surface of the skin.

Unfortunately this research has not been continued, and this is not going to be an option for European patients,

## Quality of life

T-20 studies have reported overall increases in quality of life. This was despite having to inject T-20 twice a day, on top of taking other pills,

This may be related to knowing that HIV treatment is working. Often, people who have used many treatments in the past, are eventually able to get an undetectable viral load using T-20. This is especially true when T-20 is used with other new active drugs.

## Switching from T-20 - not a drug to use forever....

T-20 may be a drug that you only need to use for a short time. If a new drug is developed that you are not resistant to, you may be able to switch from T-20 to the new drug.

In 2008 this includes the integrase

inhibitor raltegravir, a new PI called darunavir, a new NNRTI called etravirine and a CCR5 inhibitor called maraviroc.

## Other T-20 side effects

### Hypersensitivity reaction

A very small percentage of people get a 'hypersensitivity reaction' to T-20, but this is rare.

Symptoms include difficulty breathing, fever, nausea and vomiting, rash, chills, stiffening of muscles, low blood pressure and increased liver enzymes. This can be serious and life-threatening. If you have any such reaction, you should stop taking T-20 and call your doctor immediately.

### Bacterial pneumonia

People in the main T-20 studies were at higher risk of bacterial pneumonia if they used T-20 in their combination. The reason for this is not clear.

People with HIV are more susceptible to getting bacterial pneumonia than HIV-negative people.

This risk is higher if your viral load remains high, and your CD4 count is low. If you have trouble breathing, or develop a cough with a fever, then you should once again contact your doctor immediately.

### Mood changes - including euphoria

Some people have reported a feeling of euphoria when using T-20. This has often been after using T-20 for many months.

This 'euphoria' can last for up to a couple of hours after injecting. It can include a general sense of well-being, contentment, excitement, or feeling 'buzzy'.

This was not seen in the large T-20 studies but has been reported anecdotally since T-20 was approved. If you already receive T-20, then keep an eye out for this.

### Other information

Please refer to the patient information leaflet and support material in your pack for full details.

You can join a community-run email support group by sending a blank email to:

FuzeonSupport-subscribe@yahoogroups.com

Patent support material provided by the drugs manufacturer is available at:

<http://www.fuzeon.com/>

The i-Base phonenumber is a source of information about all aspects of treatment, including whether T-20 is an appropriate choice.

The phonenumber can also put you in touch with HIV-positive people who are using T-20.

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