

sanofi

Tziield[®] ▽
(teplizumab)

Your treatment handbook. Get ready for **Tziield**[®] ▽ (teplizumab)

Supporting you through
your treatment: **before,**
during, and after



This handbook is for patients who have been prescribed treatment with Tziield (teplizumab), or their caregivers. This handbook is not intended to be a substitute for medical advice.

You should also read the Patient Information Leaflet, included with your medicine, and the Guide for Patients as they contain important safety information. You can access using the links on the final page of this handbook.

Tziield is a medicine used to delay the start of Stage 3 Type 1 diabetes. This condition happens when the body cannot make enough insulin on its own and may need insulin injections. This medicine is used in adults and children aged 8 years and older who have Stage 2 Type 1 diabetes.

If you have any questions on how Tziield works or about your treatment with Tziield, ask your doctor.

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Welcome

Your doctor has prescribed Tzield (teplizumab) to delay the start of Stage 3 autoimmune Type 1 diabetes (T1D). Use this handbook to help you prepare for your infusions and find support throughout your treatment.

For further information, including answers to frequently asked questions, visit the **Tzield Patient Website** by accessing the link on the back cover.

Now, let's get started!

What if I still have questions?

If you have any questions about your treatment with Tzield, ask your doctor. You can use the space below to make a note of your doctor's contact information.

Doctor's name: _____

Phone number: _____

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Tell me about T1D

What is T1D?

Type 1 diabetes (T1D) is a progressive autoimmune disease. This means that the body's immune system mistakenly attacks healthy cells in the body.

In the case of autoimmune T1D, the immune system attacks a type of cell in the pancreas called beta cells. Healthy beta cells produce a hormone called insulin which helps your body convert glucose (sugar) from your blood into energy.

When beta cells are damaged in T1D, they cannot produce enough insulin for your body. Without insulin, the body can't move sugar from your blood into cells to use for energy, so your blood **sugar becomes too high**. Over time, this results in the symptoms of T1D.

What are the stages of T1D?

Although you may not have experienced any symptoms yet, you have been identified as having Stage 2 T1D because you have at least **2 autoantibodies** in your blood and **abnormal blood sugar** levels.

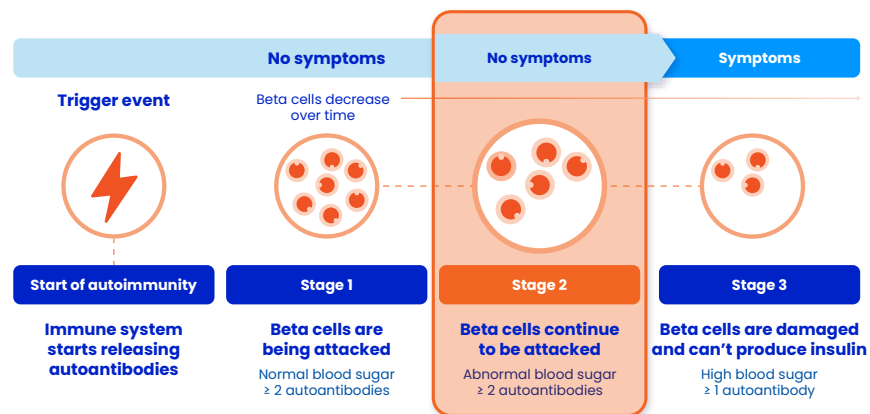
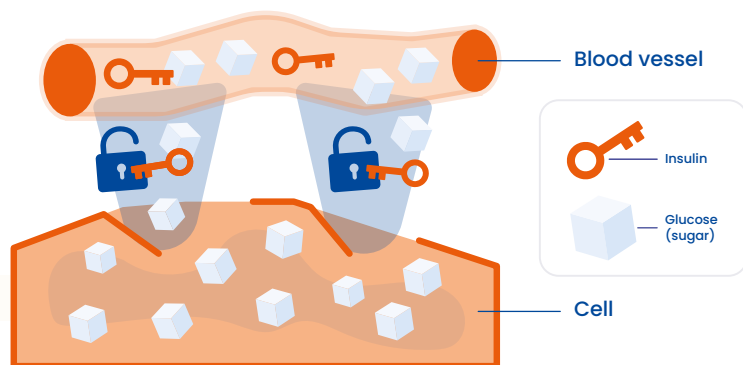
You will experience symptoms when you reach Stage 3 T1D. Tzield may help to keep you in Stage 2 for longer and delay the start of Stage 3 T1D.

Have a look at the diagram below to see the stages of T1D.

What are autoantibodies?

When your immune system attacks your beta cells, it releases proteins called autoantibodies into your blood. These autoantibodies can be detected in the blood and measured to help assess whether you have T1D and establish the stage of your disease.

Insulin is like a key that unlocks cells to let sugar in



Tell me about Tziel

What is Tziel?

Tziel is a medicine that helps to preserve the function of beta cells so that they can keep producing insulin. **This may slow the progression from Stage 2 T1D to Stage 3 T1D.**

Who is Tziel for?

Tziel is used to delay the start of Stage 3 T1D in adults and children aged 8 years and older who have Stage 2 T1D.

Your doctor has prescribed you Tziel because there is evidence of Stage 2 T1D, which is defined as having:



Two or more T1D autoantibodies



Abnormal blood sugar levels



No evidence of Type 2 diabetes



Tziel is a **2-week course** of treatment given through veins in your arm (an infusion)



How does Tziel work?

Tziel is a medicine that contains the active substance teplizumab. It belongs to a group of medicines called 'monoclonal antibodies'.

Tziel is a protein that recognises and sticks to a target. The target is a substance called CD3 that is found on a type of white blood cell – called 'T lymphocytes'.

When Tziel sticks to T lymphocytes it can help to slow down the attack on beta cells.

By slowing down the autoimmune attack on beta cells, your pancreas can keep producing insulin on its own for a little longer.

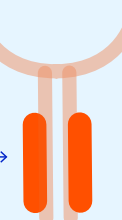


If you have any questions on how Tziel works or about your treatment with Tziel, **ask your doctor**



Tziel

CD3 antigen →



Tziel binds to CD3 antigens on T lymphocytes

T lymphocyte



What should I expect during the infusions?



Extra medicines during Tziel

Before you receive your first five Tziel infusions, **your doctor or nurse will give you some extra medicines to help prevent some potential side effects.**

These may include:

- **Ibuprofen or naproxen** (or other medicines for fever, like paracetamol)
- **An anti-sickness** (anti-nausea) medicine
- **An antihistamine** to reduce allergic reactions

These medicines may help reduce symptoms of **cytokine release syndrome (CRS)**. You can find out more about CRS in the **Guide for Patients booklet**, accessible by scanning the QR code on the back of this handbook.

Your doctor will also do blood tests to check your liver and complete blood count before and during treatment.



How is Tziel given?

Tziel will be given to you by a doctor or nurse. They will give it through a needle placed in a vein in your arm. This is called an infusion.



Where will the infusions take place?

Discuss with your doctor about how you will receive this medicine. Plan your route to the infusion centre and allow extra time for travel so you can relax and not feel rushed before treatment.



How many infusions will I have?

You will be given a Tziel infusion once a day for 14 days.

What if a day is missed?

If one of your infusions is missed, your doctor or nurse will continue the treatment on the next scheduled day to complete the 14-day course.

You won't receive two infusions on the same day.

Top tip:

You can keep track of your infusions using the infusion tracker

Top tip:

Make sure you wear **comfortable clothes and bring an extra layer** in case you get cold

Each infusion lasts for at least 30 minutes, so it's a good idea to bring something to keep you occupied.

You might want to bring:



Headphones



A book



Something to write/draw with



This handbook

What should I expect during the infusions?

What could happen during the 14 infusion days?



Tziel

Everyday you will receive your Tziel medicine through an infusion.



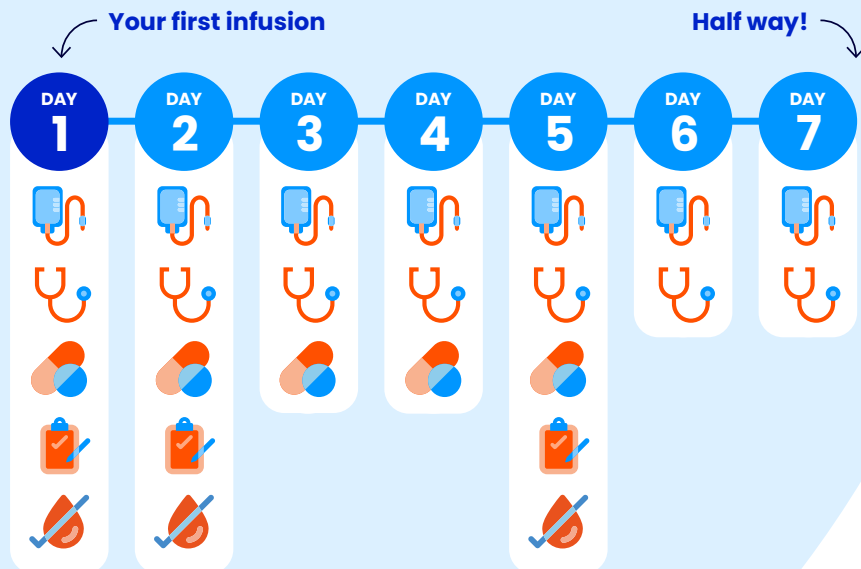
Vital signs

Every day, your care team will also check your heartbeat, breathing and temperature.



Other medicines

On some days (especially during the first 5 days), your care team might give you other medicines as well as Tziel.



Below, you'll see an example of what each day might look like. Just remember that your days might be a bit different, and that's okay.

You can **use the information in the boxes below** to understand what each icon means as you follow along.



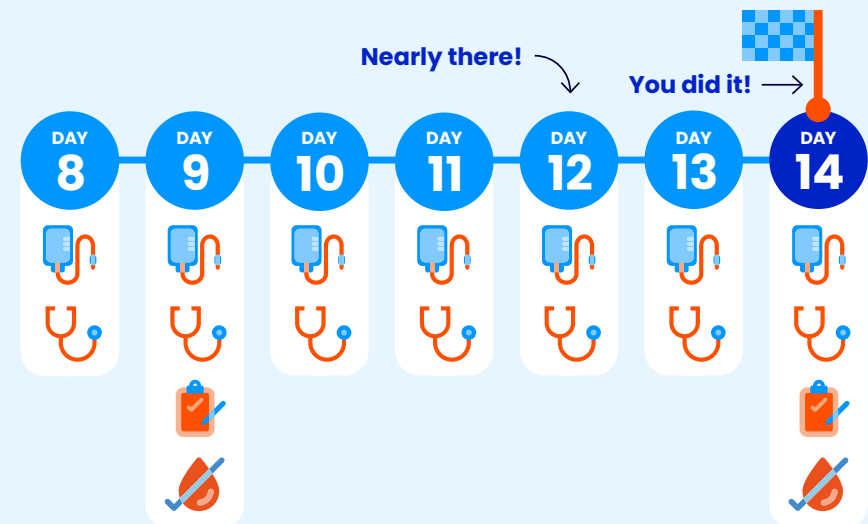
Check-ups

On some days, you might have extra checks, or none at all.



Blood tests

Sometimes, your doctor or nurse might take blood samples to see how your body is doing.



What happens when the infusions are finished?

When you have finished your Tzield infusions, your doctor will discuss a care plan with you for monitoring your blood sugar.

Why will my blood sugar be monitored after Tzield?

While Tzield may help to delay the progression from Stage 2 T1D to Stage 3, it cannot be fully prevented. Monitoring blood sugar levels helps to make sure you are diagnosed with Stage 3 T1D at the right time.

Click here to access the **Tzield Patient Website** and learn more about T1D

Talk to your doctor if you experience any symptoms of Stage 3 T1D

The symptoms for Stage 3 T1D are similar at any age, and you can remember the key symptoms as the 4Ts:



Toilet

Going for a wee more often (especially at night)



Thirsty

Being constantly thirsty and not being able to quench it



Tired

Feeling incredibly tired and lacking energy



Thinner

Losing weight without trying to, or looking thinner than usual



Genital itching or thrush



Cuts & wounds that take a long time to heal



Blurry eyesight

The 4Ts are the most common symptoms of Stage 3 T1D, but there are other symptoms that you can look out for:



Safety information

For further information on treatment with Tzield, refer to the Patient Information Leaflet and Guide for Patients booklet.

What you need to know before you are given Tzield



Severe allergic reactions

- You must not be given Tzield if you have had a severe allergic reaction to teplizumab or any of the other ingredients of this medicine
- Please refer to Section 6 of the Patient Information Leaflet 'Contents of the pack and other information' for the list of ingredients in the medicine

Tell your doctor if you, or the person you care for, have any known allergies.



Warnings and precautions

Before, during or after you are given Tzield, talk to your doctor or nurse about all your medical conditions, including if you:

- Have a serious infection – or an infection that does not go away or keeps coming back
- Have had mononucleosis (Epstein-Barr virus infection) in the past. Some patients may experience it again with Tzield treatment and it could become serious. Tell your doctor or nurse right away if you have symptoms of infection such as fever, swollen glands, or fatigue
- Are taking medicine that weakens your immune system (immunosuppressive medication)
- Have recently had, or are planning to have, a vaccine. Tzield may affect how well a vaccine works
- Have any serious side effects described in this handbook, the Guide for Patients booklet, or the Patient Information Leaflet



Other medicines, vaccines, and Tzield

Tell your doctor or nurse about the medicines you take, have recently taken, or plan to take, including:

- Prescription and non-prescription medicines
- Vitamins
- Supplements
- If you have had, or are planning to have, a **vaccine**. Tzield may affect how well a vaccine works

You should tell your doctor or nurse that you are being treated with Tzield before having a vaccine.



Pregnancy & breastfeeding

Tell your doctor or nurse if you are:

Pregnant or plan to become pregnant. Tzield may harm your unborn baby.

- Do not have Tzield during pregnancy – and at least 30 days before a planned pregnancy

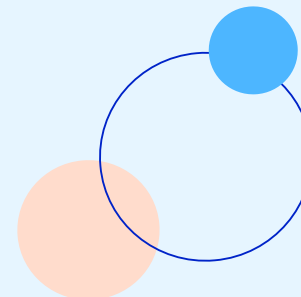
Breastfeeding or plan to breastfeed. It is not known if Tzield passes into your breast milk and if it can harm your baby.

- Talk to your doctor about the best way to feed your baby if you have Tzield
- If you are breastfeeding, it is best to pump and throw away your breast milk during treatment with Tzield – and for 20 days after treatment



Driving and using machines

Tzield is not expected to affect your ability to drive and use machines. However, if you feel tired, do not drive or use machines before discussing it with your doctor or nurse.



Safety information

Possible side effects to look out for

Your doctor will do blood tests to check your liver and complete blood counts before and during treatment with Tziel.

During and after your Tziel treatment, your doctor or nurse will check for serious side effects, as well as other side effects, and treat you as needed.

Tell your doctor or nurse if you have any of the following side effects.

Serious side effects

Cytokine release syndrome

Sometimes, treatment with Tziel can cause an immune response called cytokine release syndrome (CRS). This is most likely during the first five days of Tziel treatment, and you will be given some extra medicines to help prevent it.

Tell your doctor or nurse right away if you get any signs and symptoms of CRS, including:

- Fever
- Feeling tired
- Muscle and joint pain
- Feeling sick (nausea)
- Headache
- Increased liver enzymes in your blood

Decrease in white blood cells (lymphopenia)

Sometimes, treatment with Tziel can cause lymphopenia. This is when you have a **low number of white blood cells**, which are important cells for the immune system and help you fight infections.

- Lymphopenia is a common but serious side effect (may affect up to 1 in 10 people)
- Lymphopenia can happen after the first dose of Tziel and cell counts usually start to go back to normal after the fifth dose, though it may take longer in some people

Your doctor or nurse may pause or stop your treatment if you get liver problems, have a serious infection, or if your blood counts stay too low.

Other side effects

Very common

(may affect more than 1 in 10 people)

- Headache
- Feeling sick (nausea)
- Rash
- Fever
- Blood tests that show:
 - An increase in liver enzyme levels
 - A decrease in white blood cell count (leukopenia)
 - A decrease in number of red blood cells (anaemia)
 - A decrease in number of blood platelets (thrombocytopenia)
 - A decrease in blood bicarbonate and blood calcium levels

Common

(may affect up to 1 in 10 people)

- Cytokine release syndrome
- Inflamed nose and throat
- Diarrhoea
- Red/itchy raised bumps (hives)
- Chills

Not known

(we don't know how common these side effects are yet)

- Mononucleosis (Epstein-Barr virus) reactivation
- Vomiting
- Itchy skin
- Feeling tired
- Pain
- Illness

These are not all the possible side effects of Tziel. **Tell your doctor or nurse of any side effects and ask for medical advice**

Click here to access the **Tziel**
Patient Website or visit www.uk-tziel.com.

Click here to access the **Guide for Patients**. You may have
been given this by your doctor and you should read it.

Click here to access the **Patient Information Leaflet**.
You should read this as it contains important **safety information**.

Reporting side effects

If you get any side effects, talk to your doctor, pharmacist or nurse.
This includes any possible side effects not listed in the package leaflet.
You can also report side effects directly via the Yellow Card Scheme at
www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google
Play or Apple app Store.

Alternatively, you can report side effects to Sanofi on Tel: 0800 0902 314
or send via email to UK-drugsafety@sanofi.com. By reporting side effects,
you can help provide more information on the safety of this medicine.

▼ This medicine is subject to additional monitoring. This will allow quick
identification of new safety information. You can help by reporting any
side effects that you may get. See www.mhra.gov.uk/yellowcard for how
to report side effects.

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