

TZIELD[®]▼(teplizumab):

Guide for patients

This guide is for:



People taking TZIELD (also known as teplizumab)



Family members or friends who help care for someone taking teplizumab



Anyone legally responsible for a person taking teplizumab

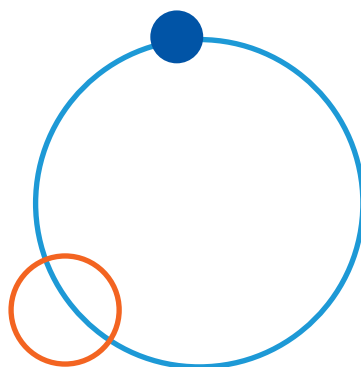
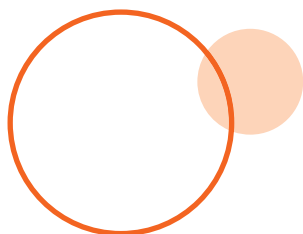
Inside, you'll find key safety information that's important to know when using teplizumab. We've made this guide to help keep you informed and safe during your treatment.

Please read the Patient Information Leaflet for complete information.

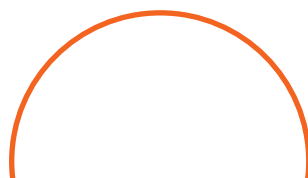
Risk minimisation material fulfils the conditions of the marketing authorisation and has been approved by the competent authority

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Hello, Let's get Started



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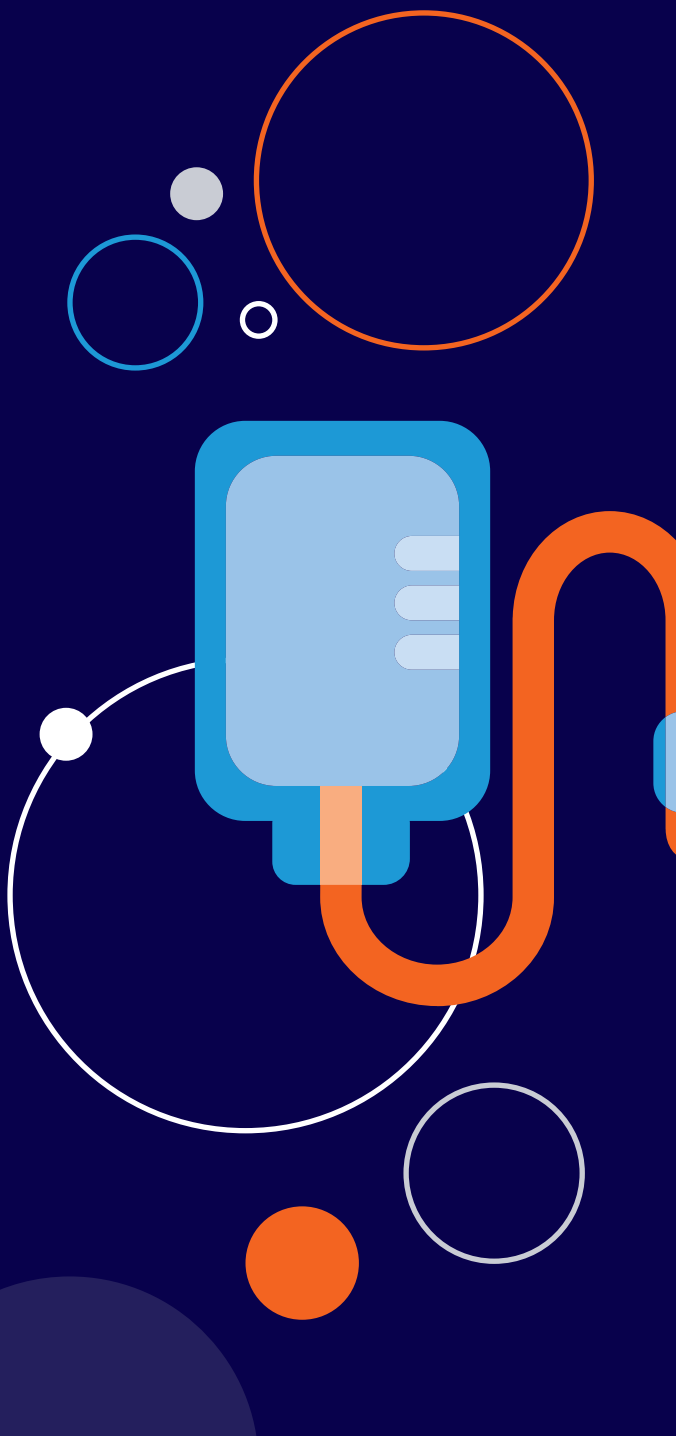


What you will learn from this guide

This guide includes important information about the treatment with teplizumab and some **serious side effects** that could occur when treated with teplizumab:

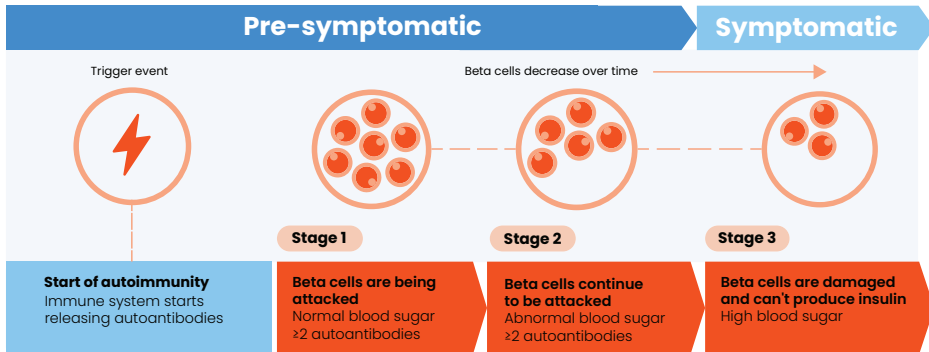
- **Cytokine Release Syndrome (CRS)**
- **Lymphopenia**
- **Serious infection**
- **Hypersensitivity reactions**

If the patient is under 18 or unable to make decisions about their care, this guide should be read by their parent, legal guardian, or caregiver.



What is autoimmune Type 1 diabetes (T1D)?

T1D happens when your body's defense system (immune system) attacks the cells in your pancreas that make insulin. This happens in stages:



Your body has special cells called beta cells. They make insulin, which helps control your blood sugar. Without insulin, the body can't move sugar from your blood into cells to use for energy, so your blood sugar becomes too high. In T1D, your body starts to attack these cells.

This attack happens slowly. At first, you won't feel sick or need insulin injections. We call this early-stage T1D. 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 early T1D and establish the stage of your disease.

Presymptomatic T1D has two parts:

Stage 1: Your body makes proteins called autoantibodies. We can find these in your blood. But your blood sugar is still normal.

Stage 2: Your blood sugar starts to go up a little. But you still don't need insulin injections.

Doctors can check for early-stage T1D with simple blood tests. These tests look for autoantibodies and measure your blood sugar.

Stage 3: Happens when many of your insulin-making cells are gone. At this point, you might start to feel unwell. You may:



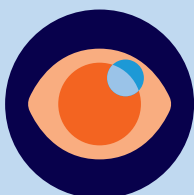
**Feel very
thirsty**



**Need to
pee a lot**



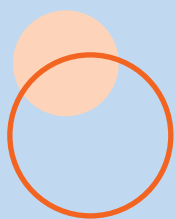
**Lose weight
without
trying**



**Have blurry
vision**



**Feel very
tired**



When you reach Stage 3, your body can't make enough insulin on its own anymore which means your blood sugar levels stay higher than normal. This means you'll need to take insulin to stay healthy and feel better.

How teplizumab works



Teplizumab is a medicine for people age 8 and older who have early T1D.

It helps delay when you'll need to start taking insulin injections.

Teplizumab may slow down the damage to some insulin-producing beta cells.

Your body may be able to continue making some of its own insulin longer naturally before you may need insulin injections.

As a result of this, teplizumab delays the onset of Stage 3 T1D.



What is the eligibility criteria for treatment with teplizumab?

Before giving you teplizumab, your doctor will do some blood tests. These tests will:

- Make sure you have Stage 2 T1D
- Check that it's safe for you to take teplizumab

Your doctor has chosen teplizumab for you because:

- Your blood tests show at least 2 proteins (called autoantibodies) of T1D
- Your blood sugar levels are higher than normal
- You don't have Type 2 diabetes

Before you start teplizumab, your doctor will:

- Take some blood to check if your liver is healthy
- Check the levels of the different cells in your blood
- Make sure you don't have certain infections

What should I do:

Tell your doctor about



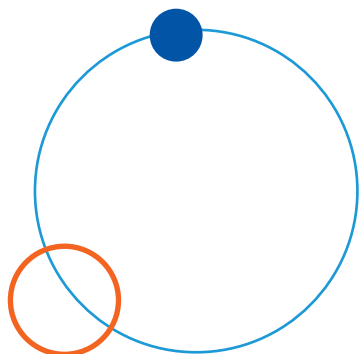
- Any allergies you have
- If you're sick or get sick often
- Any vaccines you've had recently
- If you're pregnant or breastfeeding
- If you are taking immunosuppressive medication (that weakens your immune system)

Vaccination

Teplizumab is a medicine that can change how well vaccines work in your body.

Your doctor will tell you when it's safe to get a vaccine **before or after** taking teplizumab.

For some vaccines, you might need to wait up to 1 year after taking teplizumab before you can get them.



What should I do:

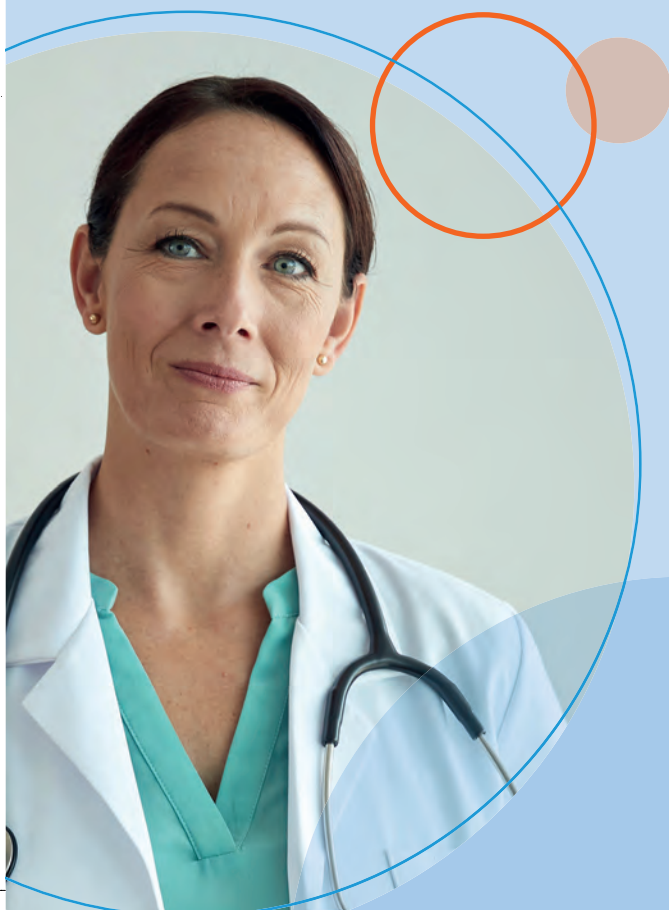
Tell your doctor about



- You've had any vaccines recently
- You're planning to get any vaccines
- You're taking or have taken teplizumab

This is important because teplizumab might affect how well vaccines work in your body.

What can I expect from treatment with teplizumab?



Your doctor will explain to you how you will receive the treatment.

● Before your teplizumab treatment

Before each teplizumab treatment (especially during the first 5 days), your doctor may give you some medicines to help prevent side effects. These might include:

1. Pain and fever medicines like ibuprofen, naproxen, or paracetamol
2. Antihistamine medicine
3. Medicine to stop feeling sick (if needed)

These medicines help reduce symptoms like fever, headache, muscle and joint pain, or feeling sick. Your doctor might continue these medicines longer if needed.



● Your teplizumab treatment

- You'll get teplizumab through a tube into your vein once a day for 14 days
- Each treatment takes at least 30 minutes
- Additional time will be needed for your doctor to prepare the treatment and for monitoring after its been given.
- For safety, you'll start with a small amount and slowly get more over the first few days
- If you miss a day, your doctor will continue the next day until you complete all 14 treatments
- You will **never get two treatments** on the same day

● During and after treatment

- Your doctor will do blood tests to check how you're doing
- They'll watch for any side effects and help you if needed
- Your doctor might pause or stop your teplizumab if you have:
 - Liver problems
 - A serious infection
 - Low blood counts that don't improve

What serious side effects might happen with teplizumab?

Possible serious side effects 	What should I do, what will my doctor do? 
<p>Cytokine release syndrome (CRS) – an overactive immune response</p> <p>Some people taking teplizumab may get something called Cytokine Release Syndrome (CRS). This usually happens in the first 5 days of treatment.</p> <p><i>You might:</i></p> <ul style="list-style-type: none"> • Have a fever • Feel tired • Have achy muscles and joints • Feel sick to your stomach • Get headaches • Have changes in your liver blood tests 	<p>Before your treatment:</p> <ul style="list-style-type: none"> • Your doctor may give you medicines for the first 5 days to help prevent side effects • These medicines help with fever, allergies, and feeling sick • You might get more of these medicines after 5 days if you need them <p>If you don't feel well:</p> <ul style="list-style-type: none"> • Tell your doctor right away if you notice any of these symptoms during your teplizumab treatment • Don't wait – getting help quickly is important <p>During treatment:</p> <ul style="list-style-type: none"> • Your doctor will take blood samples to check your liver • If your liver shows problems, your doctor might pause or stop your teplizumab treatment
<p>Decrease in white blood cells (lymphopenia)</p> <p>Teplizumab can lower some of your white blood cells called lymphocytes. These cells help your body fight germs.</p> <p>This is a serious but common side effect. It usually happens after your first dose of teplizumab. Your white blood cells usually start to return to normal after your fifth dose.</p> <p>For some people, white blood cells might stay low for longer or drop more than usual.</p>	<ul style="list-style-type: none"> • During your teplizumab treatment, your doctor will test your blood to make sure you have enough white blood cells • If your white blood cells stay too low, your doctor might pause or stop your teplizumab treatment

<h3>Serious infections</h3> <p>Teplizumab can make it harder for your body to fight germs. Some people who take teplizumab have gotten sick from bacteria and viruses.</p>	<ul style="list-style-type: none"> • Tell your doctor if you have a serious infection or an infection that won't go away or keeps coming back • If you notice signs of infection during your teplizumab treatment, tell your doctor right away • Your doctor will give you medicine for the infection and stop your teplizumab treatment
<h3>Hypersensitivity reactions: allergic reactions</h3> <p>Some people can't take teplizumab because they're very allergic to it or its ingredients. Some people who take teplizumab might have a sudden allergic reaction. This can cause:</p> <ul style="list-style-type: none"> • Fever, joint pain, and headache (doctors call this "serum sickness") • Swelling under your skin • Itchy, bumpy rash (hives) • Other types of rash • Throwing up • Trouble breathing 	<p>Before starting teplizumab:</p> <ul style="list-style-type: none"> • Tell your doctor if you've ever had a serious allergic reaction to teplizumab or any of its ingredients • If you have, you should not take teplizumab <p>During treatment:</p> <ul style="list-style-type: none"> • If you notice any signs of an allergic reaction, tell your doctor right away • Your doctor will stop teplizumab and give you medicine to help with the allergic reaction



The above side effects may be serious, although not all patients get them.





▼ This Medicinal Product is subject to additional monitoring. This will allow quick identification of new safety information.

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme, via the Yellow Card website www.mhra.gov.uk/yellowcard, the free Yellow Card app available in Apple App Store or Google Play Store, and also some clinical IT systems for healthcare professionals. Alternatively, you can call 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible. By reporting adverse drug reactions, you can help provide more information on the safety of this medicine.

Adverse drug reactions can also be reported to Sanofi: Tel: 0800 0902314. email: uk-drugsafety@sanofi.com

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