

Your treatment handbook. Get Ready for Tziel[®] ▼ (teplizumab)

**Hi! We're here
to help you get
ready for Tziel.**



This handbook is intended to support those aged 8–13 years old

This patient handbook is intended to support those aged 8–13 years old that have been prescribed treatment with Tziel and their caregivers. This patient handbook is not intended to be a substitute for medical advice.

Please read both the [Patient Information Leaflet](#) and the [Guide for Patients](#), as they contain important safety information. Information on adverse event reporting can be found at the end of this handbook.

Tziel 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 Tziel works or about your treatment with Tziel, ask your doctor.

INTRODUCTION

For parents and guardians

This handbook has been created to help your child understand their upcoming Tzield treatment. It contains information about what they can expect and what Tzield is, and outlines the support they can access along the way.

This handbook has been developed with age-appropriate information and descriptions so that your child can read it on their own (reading age 8–13 years), but you are encouraged to go through it together. Reading this handbook with your child gives you the chance to answer questions, talk about their concerns and make sure they feel supported.

Please pay close attention to the safety information in Section 7 and read it with your child, reinforcing the importance of open communication between your child and care team.

Section 8 outlines follow-up care after Tzield. While Tzield is intended to delay the progression from Stage 2 to Stage 3 Type 1 diabetes, it cannot prevent Stage 3. Ongoing symptom and blood

sugar monitoring is a vital part of your child's long-term plan to help ensure they're diagnosed with Stage 3 at the right time.

At the end of this handbook, you'll find a section called 'Tell us about you'. Please take some time to complete this with your child. It is especially helpful if your child finds verbal communication difficult or can feel anxious during appointments. Sharing details about your child's preferences and needs can help their care team provide the best possible support and spot potential side effects early.

If you have further questions on how Tzield works or about treatment with Tzield, check out the patient website [here](#).



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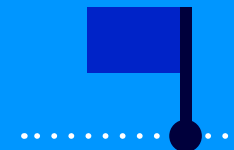
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Tell us about you



SECTION 1

Meet Dr Alex and Nurse Riley

Before you get started, let's meet the two friendly guides who will help you understand everything in this handbook.

Hi! I'm Dr Alex, and I'm an expert in Type 1 diabetes.

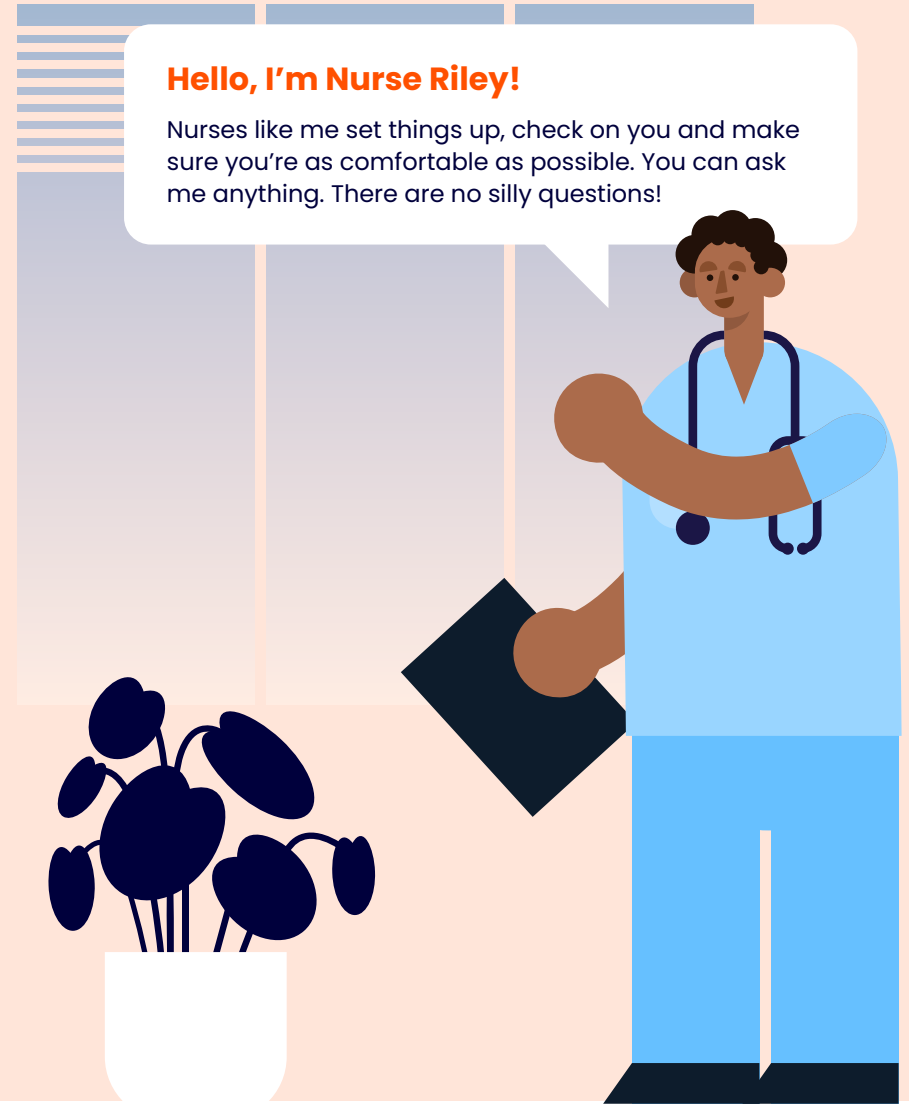
Doctors like me are in charge of your treatment with Tzield and make sure everything goes the way it should. We'll always explain what's happening so that you know what's going on.



Meet Dr Alex and Nurse Riley

Hello, I'm Nurse Riley!

Nurses like me set things up, check on you and make sure you're as comfortable as possible. You can ask me anything. There are no silly questions!



Meet Dr Alex and Nurse Riley

We're here to help and cheer for you every step of the way

If you ever feel unsure about anything, always tell your parents, your guardians or your doctor or nurse. Together, they'll make sure you have everything you need.



At the end of this handbook, you'll find a section called 'Tell us about you', where you can write down things you want your care team to know. If you need to, you can ask your parent or guardian to help you with this section.



Okay, let's get started.

SECTION 2

What is Tziel and how could it help me?

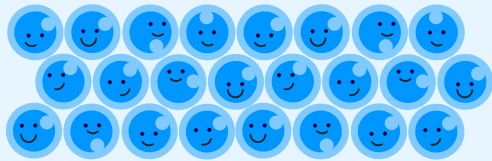
Here, you're going to learn about what Tziel is and how it could help your body.



What is Tziel and how could it help me?

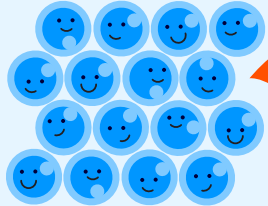
What's happening in my body right now?

Cells



Your body is made up of tiny 'building blocks' called cells. Every cell has a special job, like helping you move.

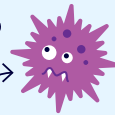
Cells



Immune system cell



Germ

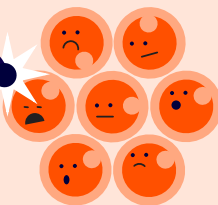


Your immune system helps protect your cells. You can think of it like a superhero team on a mission to protect you from things that can make you unwell.

In Type 1 diabetes, **some of your immune system superheroes get a bit confused** and start fighting special cells called beta cells. Over time, this can cause **the beta cells to stop working properly**.



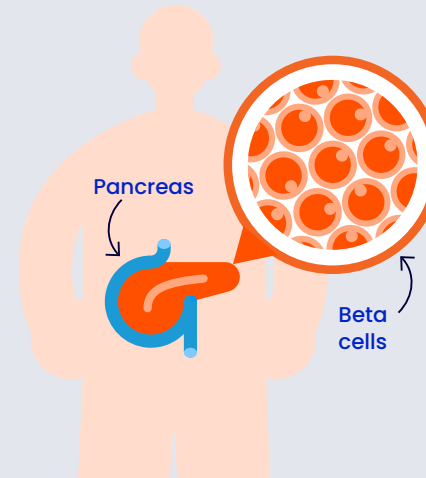
Immune system cell



Beta cells

What is Tziel and how could it help me?

About beta cells



Pancreas

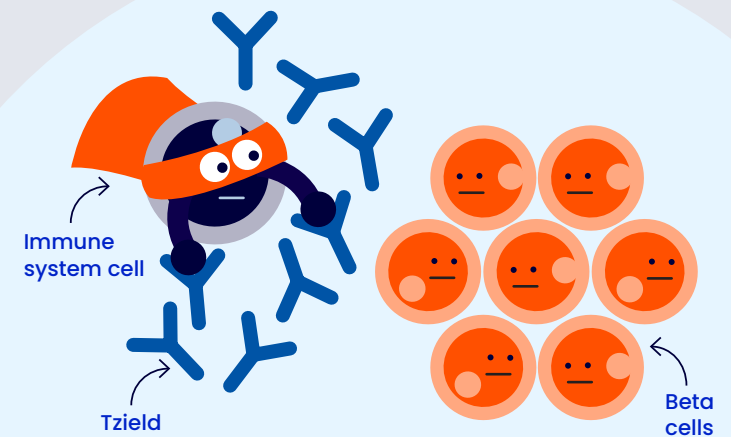
Beta cells

Beta cells have a very important job because they **make a chemical called insulin**. Insulin helps your body use **sugar for energy**.

You might feel fine now because you can't feel this happening inside you. But if too many beta cells stop working properly, **the amount of sugar in your blood can get too high**, and that can make you feel poorly.

What does Tziel do?

Tziel is a medicine that can help slow down the confused superheroes, making it easier for your beta cells to keep doing their job of producing insulin.



SECTION 3

How will I be given Tziel?

Now let's talk about what happens when you are given Tziel.



How will I be given Tziel?

Tziel is given through an infusion

You will be given Tziel by a doctor or nurse through a needle placed in a vein in your arm. This is called an infusion.

For the infusion, a small, soft and bendy tube will gently be put into your arm using a small needle. When the needle goes in, you may feel a pinch, but it will be over really fast. If you'd like, you can ask for a cream or spray to help this feel a bit easier.

Once the tube is in the right place, the needle is taken out. The tube then stays in your arm so that the medicine can travel through it.

The infusion can take 30 minutes or longer, so you may want to bring something to keep you busy while it is happening.



Remember to tell your doctor or nurse if you're worried. They will try to make you as comfortable as possible.



Make sure you read the safety information in Section 7 with your parent or guardian before your first Tziel infusion.



What your 14 days with Tziield could look like

You'll see some little icons along the way. You can **use the information in the boxes below** to understand what each icon means as you follow along.



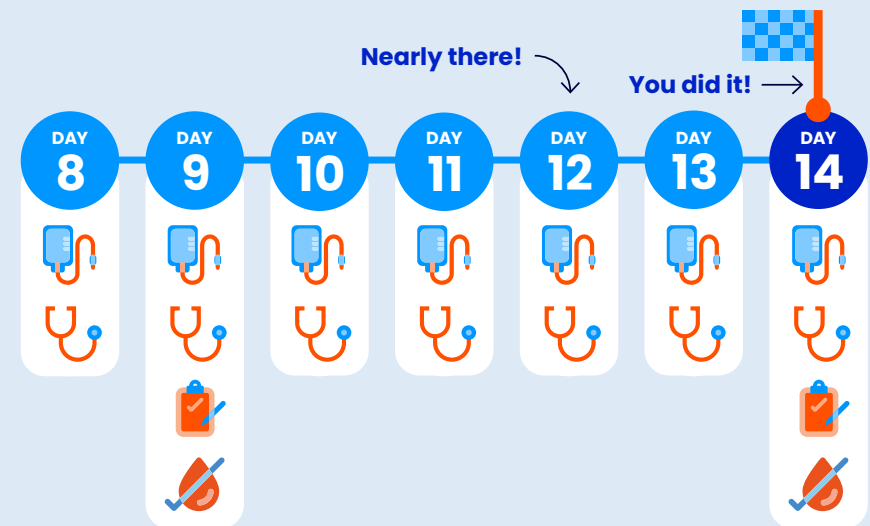
Every day, your care team will also check your heartbeat, breathing and temperature.



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



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



SECTION 4

Where will I be given Tzield and who will be there?

Where will I be given Tzield?

Your doctor or nurse will talk to you and your parent or guardian about where you can go to be given Tzield.

While you're having Tzield, you could be sitting in a chair or lying in a bed. Your care team will check on you often to make sure everything is going well and you're feeling okay.

Who will be there?

Your care team will include doctors and nurses, like Riley and me, as well as other people who will look after you.



Your doctor will make sure that you are okay to start Tzield. For the first few days, they will also give you some other medicines to make sure you're all set.



A doctor or nurse will get everything ready and put the tube in your arm. They'll also do some checks while the medicine goes in.



On some days, you might meet different doctors or nurses. Don't worry, they will know that you're having Tzield and will know what to do.

Use the space below to write down the names of the people in your care team.

My Doctor:

My Nurse(s):

Handwriting practice lines for writing names.



SECTION 5

Getting ready for Tziel



In this section, you'll find tips on getting ready, a list of things you might want to pack for your infusion, and information on who you can talk to if you want to know more about your treatment.



Getting ready for Tziel

The days leading up to my treatment

In the days leading up to Tziel, there are a few things you can do to help you stay healthy and get ready.



Try to avoid big gatherings, like birthday parties, and being around people who are sick so that you don't pick up any bugs.



Get plenty of sleep and eat healthy foods, like fruits and vegetables.



Be careful with certain sports or hobbies. Some activities may not be the best choice right now. If you're not sure, ask a parent or guardian to check with your doctor.

What should I bring with me?

You might want to bring a few things to help make you feel comfy and happy when you are receiving your treatment.

Here are some things that people might bring with them to help pass the time and make the day feel easier:

-  a favourite book or comic ☐
-  toys, a tablet or portable video game ☐
-  headphones for music or shows ☐
-  cosy clothes and a blanket ☐



What if I'm nervous or unsure?

Always make sure you tell a parent, guardian or your care team how you're feeling. Your care team are here to support you and help you feel comfortable while you're having Tziel, so it's important to let them know how you're doing.

SECTION 6

Step-by-step: How each day will go

Now let's look at what will happen on the days when you have Tzield.



1

Get up

- Get up and follow your usual routine
- Make sure you have everything you need (remember, there's a handy checklist on page 17)
- Travel to the clinic or infusion centre with your parent or guardian

2

Arrive at the clinic

- Your care team will find you and show you where you'll be having the infusion
- Your parent or guardian might have a chat with your care team before you get started with Tzield

3

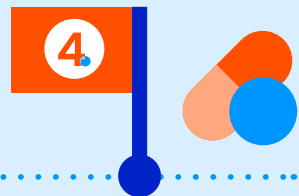
Checks

Before you are given Tzield, your care team will do some checks to make sure you are feeling okay.

- They will check your temperature to see if you are too hot
- They will check how fast and hard your heart is beating (you might have had this check before, it involves the sleeve that squeezes your arm for a few moments)
- They may also take some of your blood to do some tests (this might be done using the same tube that will be used to give you Tzield, or it might be taken from other places like your hand or arm)

Step-by-step: How each day will go

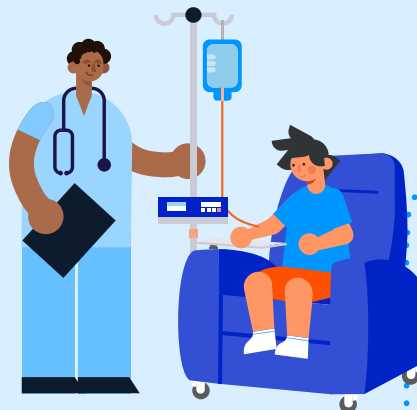
Step-by-step: How each day will go



You may be given some medicines to help during the day

Your care team might give you some medicines to help stop you from feeling:

- hot or sore
- itchy
- sick



Just before you are given Tziel

- Now is a good time to go to the toilet if you need it. But don't worry, you can always go while you're having Tziel if you need to
- When you're ready, your doctor or nurse will carefully place the small tube into your arm
- Now you're all set!



Step-by-step: How each day will go

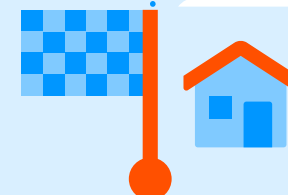


While Tziel is given

- Your care team will check on you regularly to see how you're doing
- Make sure you tell your care team, parent, or guardian how you're feeling and if you feel uncomfortable

How long does it take?

- The amount of time it takes to have Tziel each day might change, and this is normal
- Sometimes, your care team might make Tziel go in slower or even pause it. This is just to make sure that it is working properly and that you're feeling okay
- If this happens, you might meet new doctors or nurses that you haven't met before, but don't worry, they will all know what to do



When you've finished

- When you're finished, your doctor or nurse will decide if the tube will be taken out of your arm, or if you can go home with it still in
- You will need to stay with your care team for a little while to make sure that you feel okay
- When your care team have finished their checks, they will tell you when you're all done for the day
- It's normal to feel tired after Tziel. Make sure you look after yourself and have plenty of rest when you get home to prepare for the next day



SECTION 7

How might I feel during my treatment with Tziel?



Some medicines can make you feel a bit strange or poorly. This is common and usually isn't anything to worry about. This section of the booklet describes some of the things you might feel while you're having Tziel.

Go through this section with your parent or guardian so they will also know what to look out for.

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



How might I feel during my treatment with Tziel?

What you might feel

Possible side effects to look out for

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

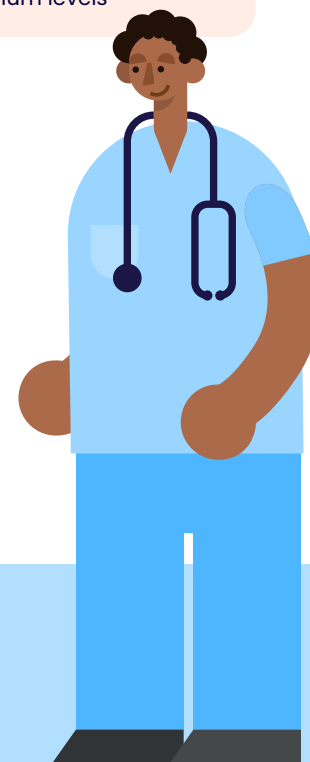
(may affect up to 1 in 10 people)

- 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



How might I feel during my treatment with Tziel?

What you might feel

Serious side effects

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



Cytokine release syndrome (CRS)

Some people taking Tziel may get an immune response called cytokine release syndrome (CRS). Tell your doctor or nurse right away if you get any signs or symptoms of CRS during treatment with Tziel. The signs and symptoms may start during the first 5 days of treatment and may include:

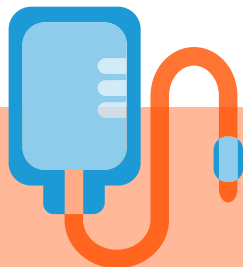
- Fever
- Feeling tired
- Muscle and joint pain
- Feeling sick (nauseous)
- Headache
- Increase liver enzymes in your blood



Decrease in white blood cells (lymphopenia)

Sometimes, treatment with Tziel can lower the number of white blood cells (lymphocytes) that you have. This is common and may affect up to 1 in 10 people. This can happen after your first dose and can affect how well your body can fight infections. Some people may get longer and more severe decreases in lymphocytes. Your white blood cell count will start to go back to normal after your fifth dose of Tziel.

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.



How might I feel during my treatment with Tziel?

What you might feel

Other medicines and Tziel

Tell your doctor or nurse about the medicines you take

This includes:

- All medicines you have recently taken, or plan to take
- Prescription and non-prescription medicines
- Vitamins
- Supplements
- If you have had, or are planning to have, a vaccine

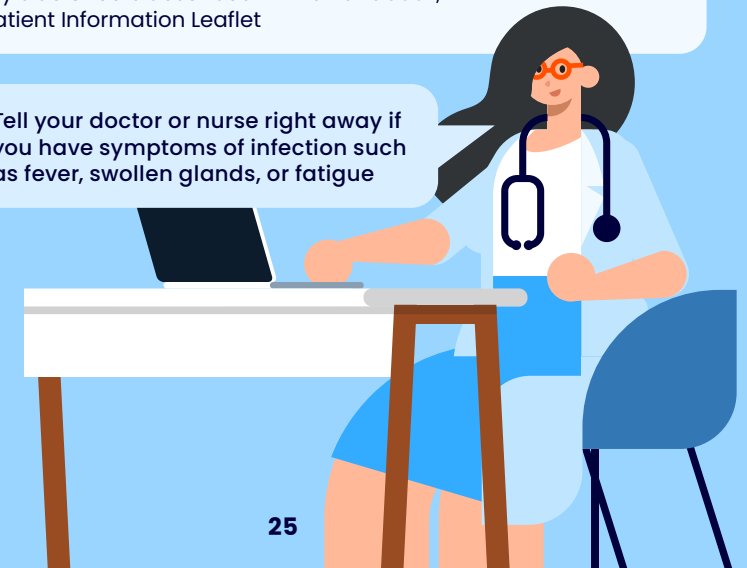
Tziel may affect how well a vaccine works. You should tell your doctor or nurse that you are being treated with Tziel before having a vaccine.

Medical history

Before, during or after you are given Tziel, 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 Tziel treatment and it could become serious
- Are taking medicine that weakens your immune system (immunosuppressive medication)
- Have any side effects described in this handbook, or the Patient Information Leaflet

Tell your doctor or nurse right away if you have symptoms of infection such as fever, swollen glands, or fatigue



SECTION 8

What happens after I finish Tzield?



After you've finished Tzield, your care team will want to check in with you from time to time. You'll also need to have some tests every now and then just to see how you are doing.



What happens after I finish Tzield?

Why do I need check-ups?



Tzield will be busy working in your body to help your beta cells keep working, but your doctor will want to check how you are doing as the effects of Tzield don't last for ever. Your care team will regularly check the levels of sugar in your blood so that they can spot any changes and give you more care when it is needed.

Sometimes, you might need to go back to the clinic, but some checks can be done at home. Your care team will let you and your parent or guardian know when and where any checks will happen.

What check-ups will I need?

Your doctor will make a check-up plan with your parent or guardian. This might include a few different types of tests to see how well your beta cells are working and how much sugar there is in your blood.

You might have something called an 'oral glucose tolerance test', or 'OGTT'. You could also have some quick finger prick tests or wear a small device that monitors your blood over time to see if there are any changes.

Looking out for changes to your body

Even though your check-ups will help spot if there are any changes in your body, it is important to keep an eye out for the following:



needing to use the toilet a lot more than usual



always feeling thirsty



feeling tired all the time



losing weight or looking thinner



itching in certain parts of your body



cuts that take a long time to heal



blurry eyesight

If you notice any of these things, make sure you tell a parent or guardian right away so they can let your doctor know.



SECTION 9

Tell us about you



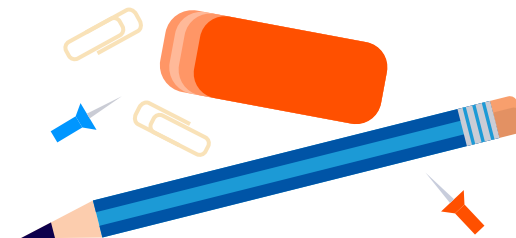
This section has been made to help your care team understand what could help you feel comfortable during your treatment with Tzield.

You can fill this out by yourself, or with a parent or guardian. It's okay if you don't know all the answers – share whatever feels right for you.



Tell us about you

Tick the boxes that feel right or add your own ideas. If you want to tell us more, there is extra space to write on the pages ahead.



How would you prefer people to talk to you?

- ☐ I like knowing as much as I can
- ☐ I'd prefer it if you only told me what I need to know
- ☐

What might help you feel comfortable during the infusion? Tick all that apply!

- ☐ Sitting in a chair
- ☐ Lying in a bed
- ☐ Being able to move around
- ☐ Having my parent or guardian close
- ☐ Having the doctor or nurse with me
- ☐ Being left alone with my book or tablet
- ☐





Tell us about you

Parents and guardians

If your child is too young or unsure what to write, use this space to note anything that helps them feel supported. Be sure to share these points with the care team.



You've made it to the end of the handbook!

We hope you found it useful and that you now feel ready for Tzield.

Remember...

If you need to revisit anything, you can always come back to this handbook or ask your care team.



Let's take a look at what you've learnt

1.

What Tzield is and how it could help you



2.

How and where you'll get Tzield



3.

How to get ready for Tzield



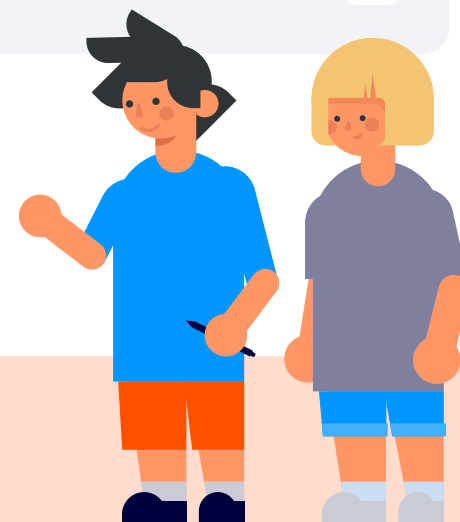
4.

What will happen during Tzield and how you might feel



5.

What happens when you've finished Tzield



To access the
Patient Information Leaflet
click [here](#).

To access the
Guide for Patients
click [here](#).

To access the **Tziel Patient Website** click [here](#) or visit www.uk-tziel.com. Here you'll find additional support and resources, with helpful frequently asked questions.



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.

sanofi

Tziel[®]
(teplizumab)

