



Package leaflet:  
Information for the patient

Tziel2 2 mg/2 mL  
concentrate for solution for infusion  
teplizumab

Is this leaflet hard to see or read?  
Phone 0800 035 2525 for help

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side affects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
  - If you have any further questions, ask your doctor or nurse.
  - If you get any side effects, talk to your doctor or nurse.
- This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Tziel is and what it is used for
2. What you need to know before you are given Tziel
3. How Tziel is given
4. Possible side effects
5. How to store Tziel
6. Contents of the pack and other information

1. What Tziel is and what it is used for

What Tziel is

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

How Tziel works

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’.

What Tziel is used for

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 adult 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.

2. What you need to know before you are given Tziel

You must not be given Tziel if:

- you have had a severe allergic reaction to teplizumab or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Before and 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 that keeps coming back.
- are taking medicine that weakens your immune system (immunosuppressive medication).
- have recently had or are planning to have a vaccine. Tziel may affect how well a vaccine works. Tell your doctor or nurse that you are being treated with Tziel before having a vaccine.
- have any of the serious side effects described in section 4.

Children

It is not known if Tziel is safe and effective in children under 8 years of age.

Other medicines and Tziel

Tell your doctor or nurse about the medicines you take, have recently taken or plan to take, including prescription and non-prescription medicines, vitamins, and other supplements.

- This also includes 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.

Pregnancy and breast-feeding

Pregnancy

Tell your doctor or nurse if you are pregnant or plan to become pregnant. Tziel may harm your unborn baby.

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

Breast-feeding

Tell your doctor or nurse if you are breast-feeding or plan to breast-feed. It is not known if Tziel 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 Tziel.
- If you are breast-feeding, it is best to pump and throw away your breast milk during treatment with Tziel – and for 20 days after treatment.

Driving and using machines

Tziel 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.

Tziel contains:

Sodium

This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially ‘sodium-free’.

Polysorbate 80

This medicine contains 0.10 mg of polysorbate 80 in each vial which is equivalent to 0.05 mg/mL. Polysorbates may cause allergic reactions. Tell your doctor if you or your child have any known allergies.

3. How Tziel is given

How Tziel is given

Tziel is given by your doctor or nurse. They will give it through a needle placed in a vein in your arm.

How often Tziel is given

You will be given Tziel infusion once every day – for 14 days. Each infusion will last at least 30 minutes.

Medicines given while you have Tziel

For the first 5 days of treatment, your doctor or nurse will give you medicines by mouth to reduce potential side effects that could be due to your Tziel infusion.

These medicines include:

- ibuprofen or naproxen – or other medicines for fever such as paracetamol
- an anti-histamine
- an anti-sickness (anti-nausea) medicine.

These medicines may help reduce symptoms of Cytokine Release Syndrome (CRS). These symptoms include fever, headache, muscle and joint pain, or feeling sick (nausea). Your doctor or nurse may decide to continue with this treatment for longer, if needed.

If you are given more Tziel than you should

Tell your doctor immediately if you think you have been given too much Tziel (an overdose). Your doctor will treat and monitor your side effects.

If you miss a Tziel infusion

If you miss a scheduled infusion, your doctor or nurse will continue your treatment on the next scheduled day. You will not get 2 infusions on the same day.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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

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

Serious side effects

Cytokine Release Syndrome (CRS)

Tell your doctor or nurse right away if you get any signs and 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 (nausea)
- headache
- increased liver enzymes in your blood.

Decrease in white blood cells (lymphocytes)

This is common and may affect up to 1 in 10 people.

- This can happen after your first dose.
- This can affect how well your body can fight infections.
- Some people may get longer and more severe decreases in lymphocytes.
- Your white blood cell counts 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.

Other side effects

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
- If any of the following are found on your blood tests:
  - Increase in liver enzyme levels
  - Decrease in white blood cell counts (leukopenia)
  - Decrease in number of red blood cells (anaemia)
  - Decrease in number of blood platelets (thrombocytopenia)
  - 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 and itchy raised bumps (hives)
- Chills

Not known (frequency cannot be estimated from the available data)

- Vomiting
- Itchy skin
- Feeling tired
- Pain
- Illness

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

Reporting of side effects

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

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tziel

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the vial after “EXP”. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C to 8°C). Do not freeze or shake the vials.

Keep the vial in the outer carton in order to protect from light. Store upright.

After dilution

If not used immediately, store the infusion solution at room temperature (15°C to 30°C) and complete infusion within 4 hours of the start of preparation. Discard the infusion solution if not administered within 4 hours of preparation.

Do not throw away medicines via wastewater or household waste. Ask your doctor or nurse how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Tziel contains

- The active substance is teplizumab.
- One vial contains 2 mg of teplizumab.
- The other ingredients (excipients) are dibasic sodium phosphate (E339), monobasic sodium phosphate (E339), polysorbate 80 (E433), sodium chloride, and water for injection.

What Tziel looks like and contents of the pack

Tziel is a concentrate for solution for infusion in a vial (2 mg/2 mL). It is a clear, colourless solution. Tziel is supplied in a carton pack containing 1, 10 or 14 vials. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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This leaflet does not contain all the information required about your medicine. If you have any questions or are not sure about anything, ask your doctor or nurse.

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The following information is intended for  
healthcare professionals only:

Preparation for intravenous administration:

- Must dilute Tziel prior to use (see Summary of Product Characteristics (SmPC) section 4.2).
- In preparation for dilution, inspect Tziel visually before use (the supplied solution is clear and colourless). Do not use Tziel if particulate matter or colouration is seen.
- Prepare Tziel using aseptic technique. Each vial is intended for single dose only.
- Prepare a:
  - Sterile glass vial with 18 mL of 0.9% sodium chloride solution for injection or
  - Polyvinylchloride (PVC) infusion bag with 18 mL of 0.9% sodium chloride solution for injection.
- Remove 2 mL of Tziel from the vial and slowly add to the 18 mL of 0.9% sodium chloride solution for injection. Mix gently by slowly inverting the vial or rocking the infusion bag. The resulting 20 mL diluted solution contains 100 mcg/ mL of teplizumab.
- Using an appropriately sized syringe (e.g., 5 mL), withdraw the volume of diluted Tziel solution required for that day's calculated dose from the 100 mcg/mL solution (see SmPC section 4.2).
- Slowly add contents of the syringe containing the Tziel dose to a PVC infusion bag containing 25 mL 0.9% sodium chloride solution for injection. Gently rock the infusion bag to ensure that the solution mixes sufficiently. Do not shake.

Important:

Based on BSA dosing requirements (e.g., >1.94 m<sup>2</sup>), 2 vials may be needed for days 5 through 14. To make sure the complete dose for each day is contained in 1 infusion bag:

- Prepare 2 dilution solutions
- Add the cumulative volume for the calculated dose to a single infusion bag

- Discard unused portion of remaining diluted Tziel solution in the sterile glass vial or PVC infusion bag.
- Start the Tziel infusion within 2 hours of preparation. If not used immediately, store the infusion solution at room temperature (15°C to 30°C) and complete infusion within 4 hours of the start of preparation. Discard the infusion solution if not administered within 4 hours of preparation.