

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

---

- ▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

## 1. Why am I being given Tzielid?

Tzielid contains the active ingredient teplizumab. Tzielid is a treatment for adults and children 8 years of age and older who have stage 2 type 1 diabetes – to delay the onset of stage 3 type 1 diabetes

For more information, see Section [1. Why am I being given Tzielid?](#) in the full CMI.

## 2. What should I know before I am given Tzielid?

Do not use if you have ever had an allergic reaction to teplizumab or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I am given Tzielid?](#) in the full CMI.

### **3. What if I am taking other medicines?**

**Some medicines may interfere with Tzielid and affect how it works.**

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How will I be given Tzielid?**

You will be given Tzielid into a vein (intravenously) as a drip infusion under the supervision of your doctor or nurse.

More instructions can be found in Section [4. How will I be given Tzielid?](#) in the full CMI.

### **5. What should I know while being given Tzielid?**

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Tzielid.</li></ul>
-----------------------------	--

	<ul style="list-style-type: none"> <li>• It is important to keep all appointments so that your doctor can see if Tzielid works for you.</li> <li>• Tell your doctor that you have had or are planning to get vaccinations.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not stop your treatment with Tzielid unless your doctor advises you to.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Tzielid 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.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Tzielid will be stored at the hospital or clinic in a refrigerator.</li> </ul>

For more information, see Section [5. What should I know while being given Tzielid?](#) in the full CMI.

## 6. Are there any side effects?

Serious side effects include Cytokine Release Syndrome (CRS) with symptoms such as fever, feeling tired, muscle and joint pain, nausea, headache and increased liver enzymes in your blood, and decrease in white blood cells (lymphocytes).

Tell your doctor or nurse straight away if you get any signs and symptoms of CRS during treatment with Tzielid.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

## Tzielid®

**Active ingredient(s):** *teplizumab*

---

### Consumer Medicine Information (CMI)

This leaflet provides important information about using Tzielid. **You should also speak to your doctor if you would like further information or if you have any concerns or questions about using Tzielid.**

**A Patient Guide is also available to you to provide important information for your treatment with Tzielid.**

**Where to find information in this leaflet:**

- [1. Why am I being given Tzielid?](#)
- [2. What should I know before I am given Tzielid?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will](#)
- [5. What should I know while being given Tzielid?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I being given Tzielid?

Tzielid contains the active ingredient teplizumab. It belongs to a group of specialised proteins called 'monoclonal antibodies'.

**Tzielid is a treatment for adults and children 8 years of age and older who have stage 2 type 1 diabetes (T1D) – to delay the onset of stage 3 T1D.**

T1D is a disease that occurs when your own immune system attacks beta cells that produce insulin in the pancreas. The destruction of these beta cells starts without any symptoms. In stage 1 T1D your blood sugar level remains normal and in stage 2 T1D it becomes elevated. Once stage 3 T1D is confirmed, you need to get insulin treatment to control blood sugar level and prevent complications.

Tzielid helps protect your beta cells by calming down the immune cells that attack them. By preserving beta cell function, Tzielid slows down the progression of T1D.

## 2. What should I know before I am given Tzielid?

### Warnings

#### Do not use Tzielid if:

- you are allergic to teplizumab, or any of the ingredients listed at the end of this leaflet. Always

check the ingredients to make sure you can use this medicine.

- you had an inactivated or mRNA vaccine within 2 weeks prior to Tzield treatment.
- you had a live vaccine within 8 weeks prior to Tzield treatment.

### **Check with your doctor if you:**

- have a serious infection or an infection that does not go away or that keeps coming back.

Some patients who have had mononucleosis (Epstein-Barr virus infection) in the past, may experience it again with Tzield treatment. Tell your doctor right away if you have symptoms of infection such as fever, swollen glands, or fatigue.

- have recently had or are planning to have a vaccine. Tzield may affect how well a vaccine works. Tell your doctor or pharmacist that you are being treated with Tzield before having a vaccine.
- have any other medical conditions.
- take any medicines for any other condition.

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## Children

The safety and efficacy of Tzield in children under 8 years of age have not been established.

## Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. If you are a woman who could become pregnant, your doctor may ask you to take a pregnancy test before you start taking this medicine. Tzield may be harmful to unborn children when taken by a woman during pregnancy. Your treatment with Tzield should be avoided during pregnancy and for at least 30 days prior to planned pregnancy.

It is not known whether Tzield passes into breast milk. Tzield was detected in animal milk. Talk to your doctor if you are breastfeeding or intend to breastfeed. If you are breastfeeding, you may consider stopping breastfeeding and pumping and throwing away breast milk during Tzield treatment and for 20 days after receiving Tzield treatment.

### **3. What if I am taking other medicines?**

Tell your doctor if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with Tzielid and affect how it works.**

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Tzielid.**

## **4. How will I be given Tzielid?**

### **How Tzielid will be given**

- You will be given Tzielid into a vein (intravenously) as a drip infusion under the supervision of your doctor or nurse.
- The dose you will receive is based on your body surface area which takes into account both your height and weight.

### **How often Tzielid will be given**

- Tzielid will be given once every day for 14 days. Each infusion will last at least 30 minutes.

### **Medicines given before a Tzielid infusion**

For the first 5 days of treatment, your doctor or nurse will give you the following medicines:

- Medicine to reduce pain and fever
- Medicine to reduce allergic reactions
- Medicine to reduce sickness and nausea

These medicines may help reduce symptoms of Cytokine Release Syndrome (CRS) such as 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 miss a Tzielid infusion**

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

### **If you are given too much Tzielid**

Your doctor or nurse will determine the correct dose for you to receive so an overdose is unlikely. If you receive too much (an overdose) your doctor or nurse will treat and monitor your side effects.

You can also contact the Poisons Information Centre (phone: 13 11 26) if you have any concerns.

## **5. What should I know while being given Tzielid?**

### **Things you should do**

#### **Keep your medical appointments**

It is important to have your infusion of Tzielid at the appropriate time to ensure that you do not miss an infusion.

Remind any doctor, nurse, pharmacist or dentist you visit that you are being given Tzielid

## **Cytokine Release Syndrome (CRS)**

Tell your doctor or nurse right away if you get any signs and symptoms of CRS during treatment with Tzielid. 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 and bilirubin in your blood

## **Decrease in white blood cells (lymphocytes)**

- 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 white blood cells.
- Your white blood cell counts will start to go back to normal after your fifth dose of Tzielid.

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.

## **Driving or 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.

## **Looking after your medicine**

Tzield will be stored at the hospital or clinic in a refrigerator at 2°C-8°C.

## **Getting rid of any unwanted medicine**

Your doctor or nurse will dispose Tzield that you no longer need or use.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## Less serious side effects

Less serious side effects	What to do
<p><b>General body:</b></p> <ul style="list-style-type: none"><li>• Fever</li><li>• Feeling tired</li><li>• Chills</li><li>• Pain</li><li>• Illness</li></ul> <p><b>Nervous system:</b></p> <ul style="list-style-type: none"><li>• Headache</li></ul> <p><b>Digestive system:</b></p> <ul style="list-style-type: none"><li>• Feeling sick (nausea)</li><li>• Diarrhoea</li><li>• Vomiting</li></ul> <p><b>Skin:</b></p> <ul style="list-style-type: none"><li>• Rash</li><li>• Itchy skin</li><li>• Red and itchy raised bumps (hives)</li></ul> <p><b>Breathing and chest:</b></p> <ul style="list-style-type: none"><li>• Inflamed nose and throat</li></ul> <p><b>Blood test - related:</b></p>	<p><b>Speak to your doctor or nurse if you have any of these symptoms.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● Increase in liver enzyme levels</li> <li>● Decrease in number of red blood cells</li> <li>● Decrease in number of blood platelets (thrombocytopenia)</li> <li>● Decrease in blood bicarbonate and blood calcium levels</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>General body:</b></p> <p><b>Cytokine Release Syndrome (CRS)</b></p> <ul style="list-style-type: none"> <li>● Fever</li> <li>● Feeling tired</li> <li>● Muscle and joint pain</li> <li>● Feeling sick (nausea)</li> <li>● Headache</li> <li>● Increased liver enzymes and bilirubin in your blood</li> </ul>	<p><b>Call your doctor or nurse straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

Serious side effects	What to do
<p data-bbox="204 255 705 358"><b>Decrease in the blood cells:</b></p> <ul data-bbox="204 398 766 501" style="list-style-type: none"> <li data-bbox="204 398 766 501">• Decrease in white blood cells (lymphocytes)</li> </ul>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## **7. Product details**

This medicine is only available with a doctor's prescription.

## What Tzield contains

<b>Active ingredient (main ingredient)</b>	teplizumab
<b>Other ingredients (inactive ingredients)</b>	dibasic sodium phosphate monobasic sodium phosphate monohydrate polysorbate 80 sodium chloride water for injections

**Do not take this medicine if you are allergic to any of these ingredients.**

## What Tzield looks like

Tzield is a clear, colourless solution for intravenous infusion in a vial (2 mg/2 mL).

Tzield is supplied in a pack of 1 vial.

Aust R 476208

## Who distributes Tzield

Tzield is supplied in Australia by:

sanofi-aventis australia pty ltd

Level 23, Tower 3

300 Barangaroo Ave

Barangaroo NSW 2000

Toll Free No: 1800 818 806

This leaflet was prepared in May 2026.