

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrTZIELD

Teplizumab for injection

This patient medication information is written for the person who will be taking **TZIELD**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This patient medication information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **TZIELD**, talk to a healthcare professional.

What TZIELD is used for:

Autoimmune type 1 diabetes (T1D) is a lifelong disease where the immune system attacks the body's insulin-making cells. It can affect anyone, no matter their age, family history, or lifestyle choices (like what they eat or how often they exercise) and gets progressively worse over time.

There are three stages of type 1 diabetes. In stages 1 and 2, there are no clear symptoms because the body can still make insulin. In stage 3, serious health problems can happen because the body can't make enough insulin to control blood sugar levels, and insulin injections might be needed.

TZIELD is for adults and children 8 years of age and older who have Stage 2 type 1 diabetes. This means that they have tested positive for 2 or more type 1 diabetes-related autoantibodies, have abnormal blood sugar levels and do not have type 2 diabetes. It is not known if TZIELD is safe and effective in children under 8 years of age.

- TZIELD is a medicine used to delay the onset of Stage 3 type 1 diabetes, which happens when the body cannot make enough insulin on its own and may require insulin injections.

How TZIELD works:

TZIELD works by slowing down the autoimmune response. TZIELD attaches to and makes less effective the immune cells that attack and destroy beta cells (insulin producing cells) in a person with T1D. As a result of this, TZIELD delays the onset of Stage 3 T1D.

The ingredients in TZIELD are:

Medicinal ingredient: Teplizumab

Non-medicinal ingredients: dibasic sodium phosphate, monobasic sodium phosphate, polysorbate 80, sodium chloride, and water for injection

TZIELD comes in the following dosage form:

2 mg/2 mL single-use vial teplizumab

Do not use TZIELD if:

- Do not use if you have experienced a severe allergic reaction, including anaphylaxis, to teplizumab or any of its excipients.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TZIELD. Talk about any health conditions or problems you may have, including if you:

- have a serious infection, or an infection that does not go away, or that keeps coming back.
- have recently received or are scheduled to receive a vaccine. TZIELD may affect how well a vaccine works. Tell your healthcare professional that you are receiving treatment with TZIELD before receiving a vaccine.

Other warnings you should know about:Pregnancy and breastfeeding:

Let your treating healthcare professional know if you:

- are pregnant or plan to become pregnant. TZIELD may harm your unborn baby. Do not receive TZIELD during pregnancy and at least 30 days before a planned pregnancy.
- are breastfeeding or plan to breastfeed. It is not known if TZIELD can pass into your breast milk and harm your baby. Talk to your healthcare professional about the best way to feed your baby if you receive TZIELD. If you are breastfeeding, you may consider pumping and throwing away your breast milk during treatment with TZIELD, and for 30 days after receiving TZIELD treatment.

Children and adolescents

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

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take TZIELD:

TZIELD is given by your healthcare professional through a needle placed in a vein in your arm (intravenous infusion).

You will receive TZIELD infusion once a day, every day, for 14 days. Each infusion will last a minimum of 30 minutes.

For the first 5 days of treatment, your healthcare professional will give you medicines by mouth to reduce potential side effects related to your TZIELD infusion. These medicines include ibuprofen or naproxen or other anti-fever medicine such as acetaminophen, an antihistamine, and an anti-nausea medicine. These medicines may help reduce symptoms of Cytokine Release Syndrome (CRS) such as fever, headache, muscle and joint pain, or nausea. Your healthcare professional may decide to continue with this treatment for longer, if needed.

Usual dose:

Your healthcare professional will administer TZIELD by intravenous infusion (over a minimum of 30 minutes). The dose you receive is based on your height and body weight, once daily for 14 consecutive days as follows:

- Day 1: 65 mcg/m²
- Day 2: 125 mcg/m²
- Day 3: 250 mcg/m²
- Day 4: 500 mcg/m²
- Days 5 through 14: 1,030 mcg/m²

Overdose:

If you think you, or a person you are caring for, have taken too much TZIELD, please contact a healthcare professional, hospital emergency department, or regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

If you miss a scheduled infusion, your healthcare professional will continue your treatment on the next scheduled day. You should not receive 2 infusions on the same day.

Possible side effects from using TZIELD:

These are not all the possible side effects you may experience when taking TZIELD. If you experience any side effects not listed in this document, please inform your healthcare professional.

TZIELD may cause serious side effects, including:

- Cytokine Release Syndrome (CRS): Signs and symptoms of CRS problems may include fever, feeling tired, muscle and joint pain, nausea, headache and increased liver enzymes in your blood.
These signs and symptoms may start during the first 5 days of TZIELD treatment. Please inform your healthcare provider right away if you develop any signs and symptoms of CRS during treatment with TZIELD.
- Decrease in white blood cells: TZIELD may cause a decrease in a type of white blood cell called lymphocytes. A decrease in white blood cells is a serious, but common side effect that can affect your body's ability to fight infections. A decrease in white blood cell counts can happen after your first dose. Your white blood cell counts will start to go back to normal after your fifth dose of TZIELD. Some people may develop longer and more severe decreases in lymphocytes.

The most common side effects may include:

- Decrease in white blood cell counts
- Rash
- Increase in liver enzyme levels
- Headache
- Nausea

- Feeling tired

Your healthcare professional will perform regular blood tests to check your liver before you start treatment and as well during treatment with TZIELD. During and after your treatment with TZIELD, your healthcare professional will monitor you for serious side effects, as well as other side effects, and provide treatment as needed. Your healthcare professional may temporarily or completely stop your treatment with TZIELD, if you develop liver problems, have a serious infection, or if your blood counts stay too low.

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Common			
Cytokine Release Syndrome: fever, feeling tired, muscle and joint pain, nausea and headache		√	
Infections: fever and chills, fatigue, generally feeling unwell		√	

Educational materials related to the management of possible serious side effects associated with the use of TZIELD have been developed for patients/caregivers. They are available upon request by contacting Medical Information via their website at www.sanofimedicalinformation.com.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Keep TZIELD vials in your refrigerator, at temperatures between 2°C and 8°C, in the original carton to protect it from light. Store upright. Do not freeze or shake the vials.

Keep out of reach and sight of children.

If you want more information about TZIELD:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website ([Drug Product Database: Access the database](http://DrugProductDatabase:Access%20the%20database)); the manufacturer's website www.sanofi.com/en/canada,

or by calling 1-800-265-7927.

This leaflet was prepared by Sanofi-Aventis Canada Inc.

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