

MEDICATION GUIDE **Rx Only**
TZIELD® (TEE-zeeld)
(teplizumab-mzwv)
injection, for intravenous use

What is the most important information I should know about TZIELD?

TZIELD may cause serious side effects, including:

- **Cytokine Release Syndrome (CRS).** Signs and symptoms of CRS problems may include:
 - fever
 - feeling tired (fatigue)
 - muscle and joint pain
 - nausea
 - headache
 - increased liver enzymes in your blood

These signs and symptoms may start during the first 5 days of TZIELD treatment. Tell 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.

Your healthcare provider will do blood tests to check your liver and your complete blood counts before you start treatment and during treatment with TZIELD. During and after your treatment with TZIELD, your healthcare provider will check for serious side effects, as well as other side effects, and treat you as needed. Your healthcare provider 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.

See "What are the possible side effects of TZIELD?" for more information about side effects.

What is TZIELD?

TZIELD is a prescription medicine used to delay the onset of Stage 3 type 1 diabetes, which is when your body can't make enough insulin on its own and may require insulin injections. 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.

Before or after receiving TZIELD, tell your healthcare provider about all your medical conditions, including if you:

- have any of the conditions or symptoms listed in the section "What is the most important information I should know about TZIELD?"
- have a serious infection or an infection that does not go away or that keeps coming back (chronic).
- have recently received or are scheduled to receive an immunization (vaccine). TZIELD may affect how well a vaccine works. Tell your healthcare provider that you are receiving treatment with TZIELD before receiving a vaccine.
- 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.
- If you become pregnant while taking TZIELD, you are encouraged to report your pregnancy to the Provention Bio's Adverse Event reporting line at 1-800-633-1610.
- are breastfeeding or plan to breast feed. It is not known if TZIELD passes into your breast milk and if it can harm your baby. Talk to your healthcare provider 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 20 days after receiving TZIELD treatment.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive TZIELD?

- TZIELD is given by a healthcare provider through a needle placed in a vein (intravenous infusion) in your arm.
- You will receive a TZIELD infusion one-time a day, every day, for 14 days. Each TZIELD infusion will last about 30 minutes.
- For the first 5 days of treatment, your healthcare provider will give you medicines by mouth before starting your TZIELD infusion. These medicines include ibuprofen, naproxen or other pain relievers such as acetaminophen, an antihistamine, and an anti-nausea medicine. These medicines may help reduce symptoms of CRS such as a fever, headache, muscle and joint pain, or nausea.
- If you miss a scheduled infusion, your healthcare provider will continue your treatment on the next scheduled day. You will not receive 2 infusions on the same day.

Tell your healthcare provider if you think something will stop you from completing treatment with TZIELD.

What are the possible side effects of TZIELD?

TZIELD may cause serious side effects including:

- See "What is the most important information I should know about TZIELD?"

The most common side effects of TZIELD include:

- rash
- leukopenia (decrease in white blood cell counts)
- headache

These are not all of the possible side effects of TZIELD. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088. You may also report side effects to Provention Bio at 1-800-633-1610.

General information about the safe and effective use of TZIELD.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about TZIELD that is written for health professionals.

What are the ingredients in TZIELD?

Active ingredient: teplizumab-mzww.

Inactive ingredients: dibasic sodium phosphate, monobasic sodium phosphate, polysorbate 80, sodium chloride, and water for injection.

Manufactured by:
Provention Bio, Inc.
Bridgewater, NJ 08807

U.S. License Number: 2170

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For more information, call 1-800-633-1610 or go to www.tzield.com.

This Medication Guide has been approved by the U.S. Food and Drug Administration.
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