

IN PATIENTS AGED 8 AND OLDER WITH STAGE 2
AUTOIMMUNE TYPE 1 DIABETES (T1D),
YOU CAN'T CONTROL IF, BUT YOU MAY IMPACT

W H : E N

Consider choosing TZIELD
(teplizumab) to modify
autoimmune T1D and
help delay **WHEN** your
patients progress¹



Patient outcomes may vary.

INDICATION: TZIELD is indicated to delay the onset of Stage 3 T1D in adult and paediatric patients 8 years of age and older with Stage 2 T1D.¹

Please see the overleaf for the NICE recommendation.

This digital leaflet is intended for healthcare professionals in the United Kingdom (UK) only.

▽ Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to the Sanofi drug safety department on Tel: 0800 0902 314. Alternatively, send via email to UK-drugsafety@sanofi.com

The Prescribing Information can be accessed at the end of this document. Please see the Summary of Product Characteristics (SmPC) for the full Safety Information for TZIELD.

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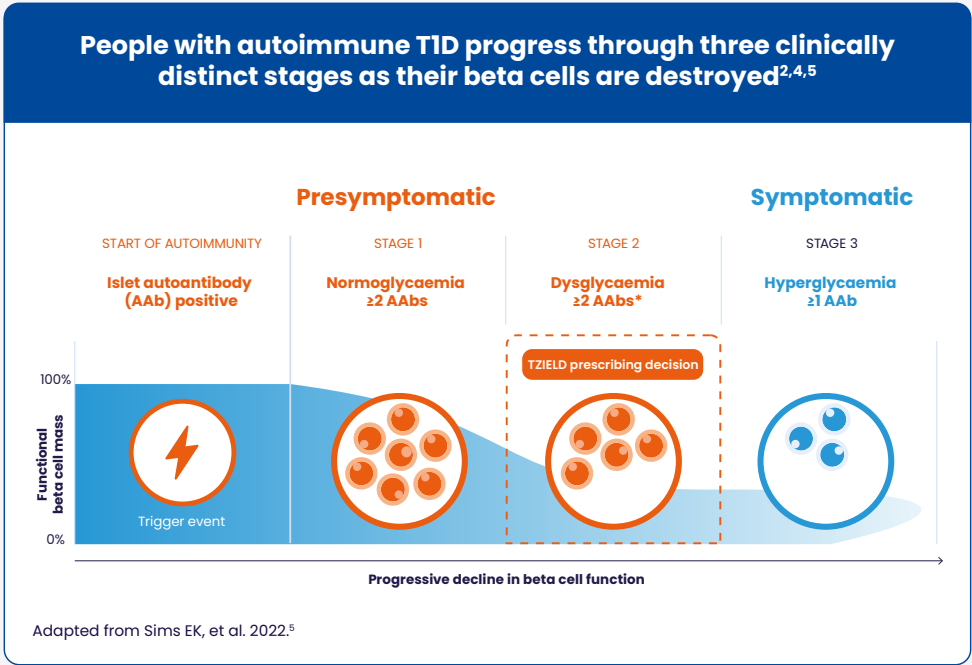
Your guide to TZIELD infusions

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Autoimmune T1D can start long before symptoms arise²

Autoimmune T1D is characterised by an immune system attack on and destruction of insulin-producing beta cells in the pancreas³



Presymptomatic Stages 1 and 2 may be collectively referred to as early-stage T1D.⁴

*Reversion to single AAb or negative status can occur in some people with previously confirmed multiple AAb positivity.⁴

Burden of T1D

Stage 3 T1D carries a substantial physical and mental burden for patients⁶

Every year, the average symptomatic autoimmune T1D (Stage 3) patient may experience:



1,460+

insulin injections^{*7}



120+

insulin pump changes^{†8}

Beyond the burden of insulin treatment, life with Stage 3 autoimmune T1D can negatively impact personal and family wellbeing:^{6,9}



Success at school and work

67% patients reported T1D had a negative impact on success at work or school^{‡6}



Relationships

43% patients reported T1D had a negative impact on family relationships^{‡6}



Mental health

>3X higher rate of depression in adults with T1D vs general public^{§10}

~1 in 3 parents experience distress at time of child's diagnosis, with ~1 in 5 reporting distress 1–4 years later^{‡11}



Sleep quality

Adults and children experience poor sleep quality related to glycaemic variability^{‡12}
Maintaining glucose levels within range at night can lead to disrupted sleep for caregivers^{‡13}

*If using injectable insulin instead of a pump. Calculated based on the minimum requirement of one basal insulin injection and three mealtime injections per day = four injections per day. $4 \times 365 = 1,460+$ injections per year.⁷

†If using an insulin pump. Calculated based on recommendation that insulin pumps should be changed every 48–72 hours (2–3 days). Therefore, pump change required 122–183 times per year ($365/3 = 121.7$ and $365/2 = 182.5$).⁸

‡From an online survey exploring the unmet needs of people with diabetes (3,350 patients with T1D), 67% of patients with T1D reported T1D having a negative impact on success at school or work; 43% reported T1D having a negative impact on family relationships.⁶

§From a systematic review of 20 studies (two studies in autoimmune T1D, five in T1D and Type 2 diabetes [T2D]; 13 in T2D) measuring the prevalence of depression in adults with diabetes across Europe and North America between 2006 and 2011.¹⁰

TZIELD is the first and only immunomodulator that delays the onset of Stage 3 T1D^{1,14,15}

Delay Stage 3 T1D through immunomodulation¹⁵

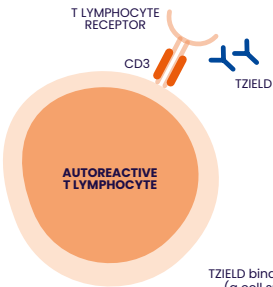


TZIELD is a humanised anti-cluster of differentiation 3 (CD3) monoclonal antibody **designed to target and modulate the autoimmune process** involved in beta cell destruction^{*,16}



TZIELD helps to preserve **beta cell function and insulin production** in the pancreas, thereby delaying the progression from presymptomatic Stage 2 to symptomatic Stage 3 autoimmune T1D¹⁷

TZIELD is indicated to delay the onset of Stage 3 T1D in adult and paediatric patients 8 years of age and older with Stage 2 T1D.¹



TZIELD binds to CD3 (a cell surface antigen present on T lymphocytes)¹

TZIELD is a single-course treatment completed over 14 consecutive days¹

TZIELD is administered by intravenous infusion over a minimum of 30 minutes using body surface area-based dosing¹

Recommended dosing schedule¹

Day	1	2	3	4	5–14
Dose (µg/m ²)	65	125	250	500	1,030

Do **NOT** administer two doses on the same day¹

If a planned infusion is missed, resume by administering **all remaining doses** on consecutive days to complete the 14-day course¹

Refer to the SmPC for full information on patient selection, storage, and preparation for intravenous administration of TZIELD.

^{*}The mechanism of action for TZIELD is not fully understood. It may involve partial agonistic signalling and deactivation of pancreatic beta cell autoreactive T lymphocytes.¹

TrialNet-10 (TN-10) study design

A phase 2, randomised, double-blind, event-driven, placebo-controlled study in 76 patients, 8–49 years of age with Stage 2 T1D and a relative diagnosed with Stage 3 T1D ^{*1,18}

Primary analysis ^{1,18}						Extended analysis ¹⁹	
Randomisation (N=76) ^{1,18} Randomised through rolling enrolment and stratified according to TrialNet site, age, and second OGTT result before treatment	TZIELD (n=44) [†]						
	Day Dose (µg/m ²)	0 51	1 103	2 207	3 413		
	Placebo (saline; n=32)						
Median follow-up time: 745 days (range 74–2,683 days) ¹⁸ Patients were followed in a blinded fashion until 40 patients had developed Stage 3 clinical T1D ¹⁸						Median follow-up time: 80.46 months ¹⁹	
Primary efficacy endpoint: Time from randomisation to diagnosis of Stage 3 clinical T1D. ¹							

TZIELD dosing in the TN-10 trial is different to that recommended in the approved SmPC.^{1,18} However, total drug exposure was comparable to that achieved with the recommended total TZIELD dosage.¹



Access the dosing calculator on the [TZIELD website](#)

^{*}Stage 2 is defined as having two or more pancreatic islet AABs (glutamic acid decarboxylase 65 AAb, insulin AAb, islet cell AAb, insulinoma-associated antigen 2 AAb, islet cell AAb, and zinc transporter 8 AAb) and dysglycaemia on an oral glucose tolerance test (OGTT).¹
[†]Criteria for Stage 3 T1D were based on glucose testing or the presence of unequivocal hyperglycaemia or hyperglycaemia crisis.²⁰

TN-10 primary analysis

In the primary analysis of the TN-10 study:^{1,18}

2x more time in Stage 2 autoimmune T1D with TZIELD vs placebo

Median time to diagnosis of Stage 3 autoimmune T1D:

TZIELD: 48.4 months
Placebo: 24.4 months

N=76; hazard ratio (HR) 0.41; 95% confidence interval (CI), 0.22–0.78; $P=0.0066$ by an adjusted Cox proportional-hazards model stratified by age and OGTT status at randomisation.^{1,18} Median follow-up time was 745 days (range: 74–2,683 days).¹⁸

In TN-10, Stage 3 T1D was diagnosed in 20 (45%) patients treated with TZIELD and 23 (72%) patients treated with placebo.¹

What could more time in Stage 2 T1D mean for your patients?

For your eligible patients, more time in Stage 2 T1D could mean:



More insulin-free years^{21,22}

Delaying the **social stigma** and **lifestyle disruptions** that come with managing T1D^{21,23}



Time for vigilant monitoring of signs and symptoms of DKA²²

To **reduce the risk** of hospitalisation with DKA⁴

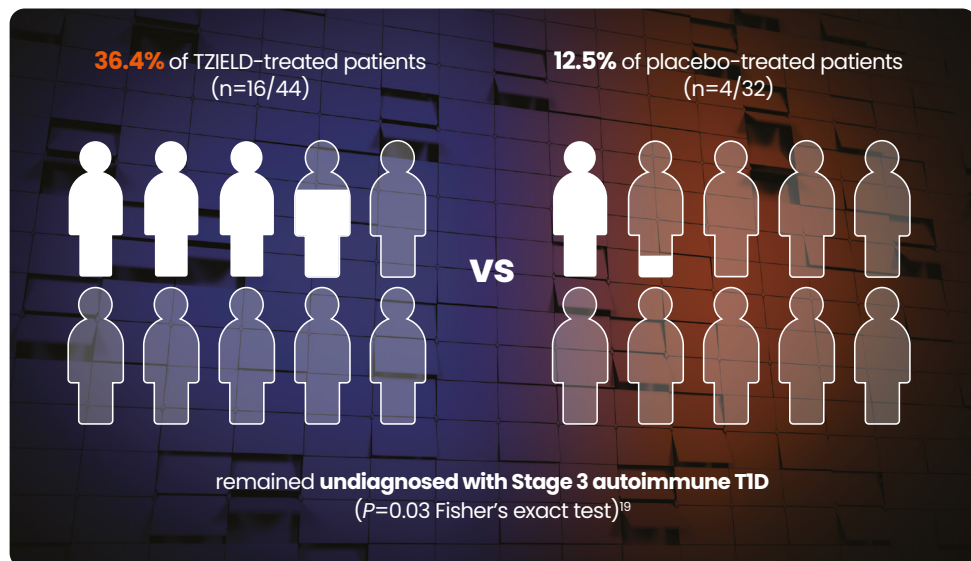


Increased opportunities to learn about glycaemic control⁴

So your patients can learn how to properly **manage** their disease²⁴

TN-10 extended follow-up analysis

In an extended analysis of TN-10, after a median follow-up time of **7 years***



The median time to Stage 3 T1D was ~4 years in the TZIELD group vs ~2 years in the placebo group (P=0.0026)^{†19}



The TN-10 study was relatively small at the start, and patient numbers decreased throughout follow-up.^{1,18} Therefore, definitive conclusions cannot be derived from these data. Patient results may vary.

*The median follow-up time was 80.46 months.¹⁹

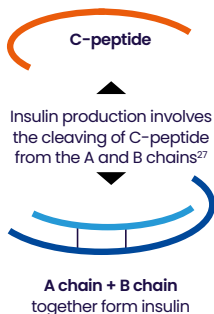
†The median time to Stage 3 T1D was ~4 years (52.2 months [95% CI, 30.5–86.7]) with TZIELD and ~2 years (27.3 months [95% CI, 9.5–48.4]) in the placebo group; P=0.0026 log-rank test.¹⁹

Beta cell dysfunction can be measured using C-peptide²⁵

Insulin and C-peptide are secreted in equimolar amounts following the cleavage of proinsulin^{25,26}

Compared to insulin, C-peptide has a slower rate of degradation and a less variable rate of clearance, making it a more stable reflection of beta cell function.^{25,26}

Proinsulin is composed of three domains:
— C-peptide — A chain — B chain



Insulin production involves the cleaving of C-peptide from the A and B chains²⁷

C-peptide^{25,28}

Reliable measure of beta cell function due to:

- constant rate of clearance
- slower rate of degradation

Insulin^{25,28}

Difficult to measure accurately due to:

- variable rate of clearance
- impact of exogenous insulin
- impact of endogenous insulin antibodies

Adapted from Yang Y, et al. 2010.²⁷

Greater residual beta cell function, as indicated by higher UCPCR (urinary C-peptide-to-creatinine-ratio), **correlates with longer time in range** (glucose concentration 3.9–10 mmol/L), **lower HbA1c** (glycated haemoglobin) and **lower total daily insulin dose***²⁹

*Cross-sectional cohort study of 489 Dutch adults with autoimmune T1D (median duration 15 years) assessing associations between residual beta cell function (measured by UCPCR), alpha cell function (glucagon/glucose ratio) and CGM (continuous glucose monitoring) metrics, including time in range, variability, and hypoglycaemia.²⁹

TZIELD changed the biological course of T1D by improving beta cell function vs placebo in TN-10¹⁷

In an extended analysis of TN-10, after a median follow-up time of **7 years***



TZIELD was associated with improved beta cell function vs placebo, as measured by average on-study C-peptide AUC

The average on-study C-peptide area under curve (AUC) was greater for patients treated with TZIELD vs placebo (1.94 vs 1.72 pmol/mL; $P=0.006$)^{*17}



TZIELD was associated with a reverse in C-peptide decline during the first 6 months of treatment

Compared to pre-treatment levels, patients treated with TZIELD had significantly increased C-peptide AUC 6 months after enrolment (change from baseline +0.17 pmol/mL; $P=0.04$)^{†17}



Preservation of C-peptide was maintained until the last 6 months preceding Stage 3 T1D diagnosis

Less C-peptide AUC was lost over time in patients treated with TZIELD compared to placebo ($P=0.04$)^{‡17}

There are currently no long-term data on the effect of beta-cell preservation, as measured by C-peptide, in patients with Stage 2 T1D.

*Unadjusted mean (IQR) for TZIELD (1.96 [1.48 to 2.61] pmol/mL; N=44) vs placebo (1.68 [1.32 to 2.11] pmol/mL; N=32). When adjusted for age and baseline C-peptide AUC, the difference was highly significant; $P=0.006$.¹⁷

†Mean C-peptide AUC for TZIELD at 6 months (2.06 [1.55 to 2.58] pmol/mL) vs baseline (1.89 [1.47 to 2.17] pmol/mL); Wilcoxon paired test, $P=0.04$. Placebo at 6 months (1.68 [1.2 to 2.15] pmol/mL) vs baseline (1.83 [1.56 to 2.36] pmol/mL); Wilcoxon paired test, $P>0.05$.¹⁷

‡The median slope for C-peptide AUC until the end of the study period or until 6 months before diagnosis with Stage 3 T1D significantly declined in the placebo group but not in the TZIELD group: the median slope for placebo was significantly less than 0 (-0.00382 [-0.0107 to 0.000755]; Wilcoxon one-sample, $P=0.04$); the median slope for TZIELD was not significantly different from 0 (-0.000294 [-0.00372 to 0.00304]; Wilcoxon one-sample, $P=0.63$).¹⁷ Less C-peptide was lost over time with TZIELD vs placebo (Wilcoxon two-sample, $P=0.04$).¹⁷

TZIELD safety profile

The safety profile of TZIELD has been evaluated in a pool of adult and paediatric patients across five controlled clinical studies¹

Adverse reactions occurring in ≥5% of patients in the pooled safety analysis of clinical studies ¹			
System organ class	Frequency		
	Very common (≥1/10)	Common (≥1/100 to <1/10)	Not known [†]
Infections and infestations		Infections*	Epstein-Barr virus (EBV) reactivation
Blood and lymphatic system disorders	Lymphopenia, Leukopenia, Neutropenia, Decreased haemoglobin, Thrombocytopenia		
Immune system disorders		Cytokine release syndrome (CRS)	
Nervous system disorders	Headache		
Respiratory, thoracic and mediastinal disorders		Nasopharyngitis	
Gastrointestinal disorders	Nausea	Diarrhoea	Vomiting
Skin and subcutaneous tissue disorders	Rash, Pruritus	Urticaria	Rash Pruritic
General disorders and administration site conditions	Pyrexia	Chills	Fatigue, Pain, Illness
Investigations	Increased alanine aminotransferase (ALT), Increased aspartate aminotransferase (AST), Decreased blood bicarbonate, Decreased blood calcium		

Adapted from TZIELD (teplizumab) UK SmPC.¹

Lymphopenia, leukopenia, neutropenia, decreased blood bicarbonate, and rash were the most frequently reported adverse reactions, which occurred at a higher frequency in the TZIELD group compared to the control group.¹

CRS is a systemic inflammatory response that can be triggered by TZIELD.^{1,30} The symptoms can be unspecific and range from mild to moderate.^{1,30}

Lymphopenia is a low number of white blood cells and can affect how well patients fight infections.³¹

No drug interaction studies have been performed¹

Refer to section 4.8 of the SmPC for more information regarding these and other adverse reactions.
*Reported as serious – see ‘Description of selected adverse reactions’ in the SmPC for more information.
†Cannot be estimated from available data.

Serious adverse reactions have been reported with greater frequency in TZIELD-treated patients vs placebo-treated patients in TN-10¹

Serious adverse reactions in TN-10¹

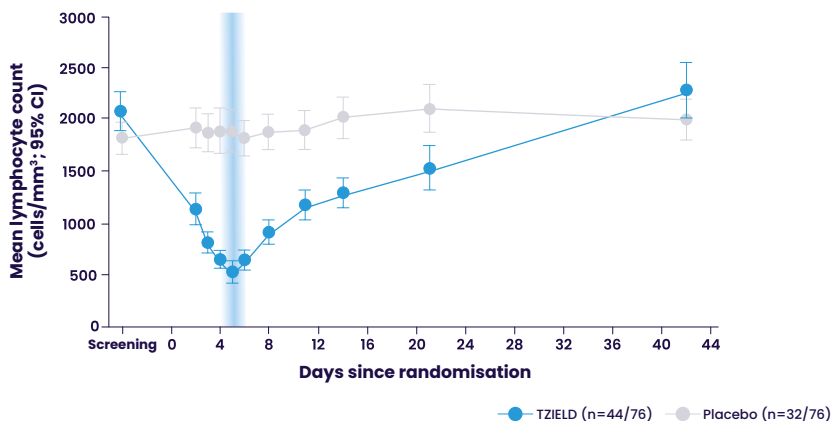
Adverse reaction, % (n)	TZIELD (n=44/76)	Placebo (n=32/76)
CRS	2% (1)	0% (0)
Serious infections*	9% (4)	0% (0)
Hypersensitivity reactions and serum sickness	2% (1)	0% (0)
Lymphopenia	73% (32)	6% (2)

Adapted from TZIELD (teplizumab) UK SmPC.¹

Lymphopenia

Lymphopenia is an expected and very common adverse reaction to TZIELD.^{1,18} In clinical trials, 80% of patients treated with TZIELD developed lymphopenia compared to 17% of patients in the control group.¹

TN-10: Average lymphocyte count nadir occurred at Day 5 of treatment, with recovery and return to baseline by Week 6 in most patients¹⁸



Adapted from Herold KC, et al. 2019.¹⁸

*Serious infections included cellulitis, gastroenteritis, pneumonia, and wound infection any time during or after the first dose of study treatment.¹

Safety profile

Guidance for lymphopenia¹



Monitor white blood cell counts during the 2-week treatment period



If prolonged severe lymphopenia (<500 cells/ μ L, lasting 1 week or longer) develops, discontinue TZIELD

Cytokine release syndrome (CRS)

In clinical trials, CRS was reported in 6% (n=46/791) of patients treated with TZIELD vs 1% (n=3/245) of patients in the control group during the treatment period and through 28 days after the last study drug administration.^{1,14}

- 13% of these CRS cases (n=6/46) were serious adverse reactions¹
- 88% of all CRS events (n=43/49) were grade 1 or 2 in severity and treated with non-prescription medications^{*14}

CRS manifestations in patients treated with TZIELD included fever, nausea, fatigue, headache, myalgia, arthralgia, increased ALT, increased AST, and increased total bilirubin, and typically occurred during the first 5 days of treatment.¹

Mitigation guidance for CRS¹

- Premedicate with antipyretics, antihistamines, and/or antiemetics prior to TZIELD treatment
- Monitor liver enzymes and bilirubin during treatment. Discontinue TZIELD treatment in patients who develop:
 - elevated ALT or AST >5 X upper limit of normal (ULN) **OR**
 - bilirubin >3 X ULN
- Treat symptoms of CRS with antipyretics, antihistamines, and/or antiemetics
- If severe CRS develops, consider temporarily pausing dosing for 1–2 days (and administer the remaining doses to complete the full 14-day course on consecutive days) or discontinuing treatment

^{*}CRS grades range from 1 (mild) to 4 (severe).³⁰

Special warnings and precautions for use

Serious infections

Bacterial and viral infections have occurred in TZIELD-treated patients including gastroenteritis, cellulitis, pneumonia, abscess and sepsis.¹

In clinical trials, patients treated with TZIELD had a higher rate of serious infections (3.5%) than patients in the control group (2%).¹ Epstein-Barr Virus (EBV) reactivation may occur in patients treated with TZIELD. In patients with co-morbid conditions predisposing them to significant immunocompromise, clinical course of EBV reactivation may present with increased severity.¹

Patients should be tested for active EBV and CMV infection prior to starting treatment. Use of TZIELD is not recommended in patients with active serious infection, laboratory or clinical evidence of acute infection with EBV or CMV, or chronic infection other than localised skin infections. Lymphocyte count monitoring requirements and discontinuation recommendations should be followed.¹

Management considerations¹

- Monitor patients for signs and symptoms of infection, including viral reactivation, during and for at least 2 months after the last TZIELD treatment dose
- If viral reactivation is suspected, viral load should be assessed (e.g., PCR)
- If serious infection or viral reactivation develops, treat appropriately. If these infections occur during treatment discontinue TZIELD

Hypersensitivity reactions

Acute hypersensitivity reactions, including serum sickness, angioedema, urticaria, rash, vomiting and bronchospasm occurred in TZIELD-treated patients.¹

In clinical trials, anaphylaxis, angioedema, rash, and urticaria were reported with greater frequency in TZIELD-treated patients vs the control group.¹

Management considerations¹

- If severe hypersensitivity reactions occur, discontinue use of TZIELD and treat promptly

Concomitant immunosuppressive medication

In T1D studies, the safety and efficacy of TZIELD in combination with immunosuppressive medication have not been evaluated. Caution should be exercised when considering concomitant use of immunosuppressive medication.¹

Safety profile



Vaccinations

The safety of immunisation with live-attenuated vaccines in patients treated with TZIELD has not been studied. TZIELD may interfere with the immune response to vaccination and decrease vaccine efficacy.¹

Administer all age-appropriate vaccinations prior to starting TZIELD¹

- Inactivated or messenger ribonucleic acid (mRNA) vaccinations are not recommended within the 2 weeks prior to TZIELD treatment, during treatment, or 6 weeks after completion of treatment
- Live-attenuated vaccinations are not recommended within the 8 weeks prior to TZIELD treatment, during treatment, or up to 52 weeks after treatment

Incompatibilities¹

- In the absence of compatibility studies, TZIELD should not be mixed with other medicinal products
- Do not add or simultaneously infuse other medicinal products through the same intravenous line
- This medicinal product should be prepared and administered as instructed in section 4.2 and section 6.6 of the SmPC

List of excipients¹

- Dibasic sodium phosphate (E339)
- Monobasic sodium phosphate (E339)
- Polysorbate 80 (E433)
- Sodium chloride
- Water for injection



Effects on ability to drive and use machines

Fatigue has been reported in patients taking TZIELD and this should be taken into account when driving or using machines.¹

Pregnancy¹

- Available case reports from clinical trials with TZIELD are insufficient to identify a drug-associated risk of major birth defects, miscarriage or other adverse maternal or foetal outcomes
- Although there are no data on TZIELD, monoclonal antibodies can be actively transported across the placenta, and TZIELD may cause immunosuppression in the utero-exposed infant
- To minimise exposure to a foetus, **avoid use of TZIELD during pregnancy and for at least 30 days prior to planned pregnancy**

Breastfeeding¹

- There are no data on the presence of TZIELD in human milk, effects on milk production, or effects on the breastfed child
- As endogenous maternal immunoglobulin G (IgG) and monoclonal antibodies are transferred into human milk, a lactating woman may interrupt breastfeeding and pump and discard breast milk during treatment and for 20 days after TZIELD administration to minimise drug exposure to a breastfed child

Fertility¹

There are no clinical trial data available for TZIELD on the effects on fertility.¹

See section 4.8 of the SmPC for additional safety information

Glossary

Beta Cell Function

The endogenous insulin secretory capacity of pancreatic beta cells. In clinical practice and trials, this is most accurately and commonly estimated by measuring C-peptide levels.^{25,28}

C-peptide

A 31-amino-acid peptide that is cleaved from proinsulin and co-secreted from pancreatic beta cells in equimolar amounts with endogenous insulin. Because it has a slower degradation rate and a more constant peripheral clearance rate than insulin, it is utilised as a reliable and stable surrogate biomarker for assessing residual pancreatic beta cell function.^{25,28}

Early-stage Type 1 Diabetes (T1D)

A collective term used to refer to the presymptomatic stages of autoimmune T1D, comprising both Stage 1 and Stage 2 T1D.⁴

Islet Autoantibodies (AABs)

Biomarkers indicating an autoimmune response against pancreatic beta cells. The primary autoantibodies used to identify risk and stage T1D include those against glutamic acid decarboxylase 65 (GADA), insulin (IAA), insulinoma-associated antigen 2 (IA-2A), zinc transporter 8 (ZnT8A), and islet cells (ICA).¹⁴

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Abbreviations

AAb, autoantibody; **ALT**, alanine aminotransferase; **AST**, aspartate aminotransferase; **AUC**, area under curve; **CD3**, cluster of differentiation 3; **CGM**, continuous glucose monitoring; **CI**, confidence interval; **CRS**, cytokine release syndrome; **EBV**, Epstein-Barr virus; **HbA1c**, glycated haemoglobin; **HR**, hazard ratio; **IgG**, immunoglobulin G; **mRNA**, messenger ribonucleic acid; **NICE**, National Institute for Health and Care Excellence; **OGTT**, oral glucose tolerance test; **SmPC**, Summary of Product Characteristics; **T1D**, Type 1 diabetes; **T2D**, Type 2 diabetes; **UCPCR**, urinary-C-peptide-to-creatinine-ratio; **UK**, United Kingdom; **ULN**, upper limit of normal.

**Access the
TZIELD SmPC [here](#)**

**Access the
TZIELD prescribing
information [here](#)**

Recommended by NICE

**Access the NICE recommendation³²
on the TZIELD website [here](#)**

TZIELD is recommended by the National Institute for Health and Care Excellence (NICE), within its marketing authorisation, for delaying the onset of Stage 3 type 1 diabetes (T1D) in people 8 years and over with Stage 2 T1D, subject to the commercial arrangement as outlined in the NICE guidance.³²

