Teizeild® ▽
(teplizumab)

IN PATIENTS AGED 8 AND OLDER WITH STAGE 2 T1D,[1]

YOU CAN'T CONTROL IF, BUT YOU MAY IMPACT

WH:EN

Choose to target the underlying autoimmune attack in type 1 diabetes (T1D) with Teizeild (teplizumab), and help delay WHEN your patients progress[1]

Teizeild 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]

Intended for healthcare professionals.

▽ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

This medicinal product is subject to risk minimisation measures. Please refer to the Summary of Product Characteristics and Guide for Healthcare Professionals for more information.

The information provided is based on the approved label of the European Medicines Agency. Before prescribing the product, always refer to the Summary of Product Characteristics available in your country.

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sanofi

Teizeild is the first and only therapy approved to delay progression to clinical autoimmune T1D (Stage 3)[1,2]

Teizeild is pioneering **a new era of therapy** as the **first intervention** designed to target the **immunological root cause** of autoimmune T1D.[1-4]

Giving people living with early stage T1D more time at Stage 2 may:

- enable more **insulin-free years**[2,3]
- **reduce workplace & lifestyle disruptions** associated with clinical autoimmune T1D, such as increased sick leave and carbohydrate counting[8,9]
- provide **more time free from the emotional challenges of a clinical diagnosis and more time to psychologically prepare** for Stage 3 onset[4–6]
- **allow for vigilant monitoring** of signs and symptoms of DKA[10]
- **increase opportunities to learn about glycaemic control** to achieve glycaemic targets, reducing the risk of macro- and microvascular complications[4,7]

Autoantibody screening can help you to identify patients with presymptomatic Stage 2 T1D.[5] Individuals with two or more autoantibodies and dysglycaemia, indicating Stage 2 T1D, may be eligible for Teizeild.[1]

Stage 2 T1D confirmed by[1]:

- at least two positive pancreatic islet cell autoantibodies
- dysglycaemia without overt hyperglycaemia
- Patients must not have T2D or secondary dysglycaemia related to a condition other than autoimmune T1D

Dysglycemia:

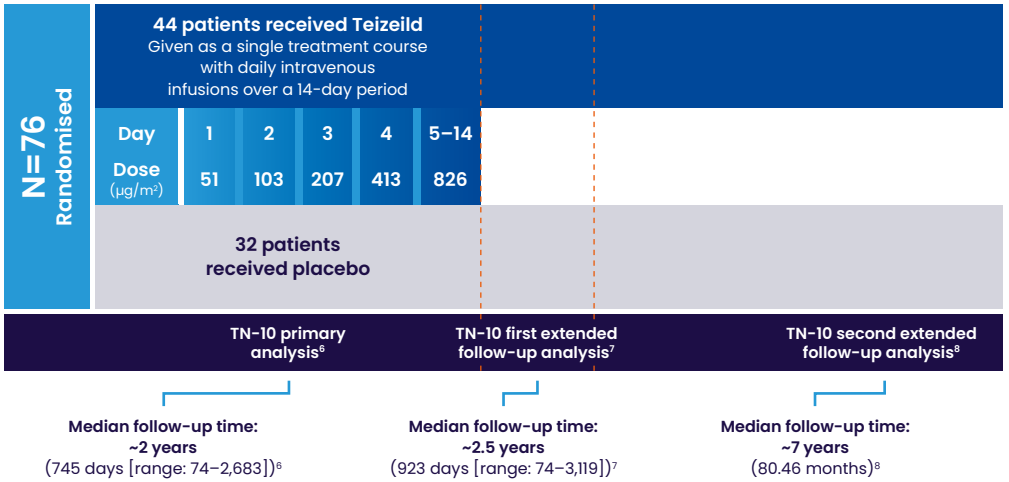
- IFG: FPG 100–125 mg/dL (5.6–6.9 mmol/L) or
- IGT: 2-h PG 140–199 mg/dL (7.8–11.0 mmol/L) or
- A1C 5.7–6.4% (39–47 mmol/mol) or ≥10% increase in A1C

IFG, impaired fasting glucose; FPG, fasting plasma glucose; IGT, impaired glucose tolerance; 2-h PG, 2-h plasma glucose
Alternative additional stage 2 diagnostic criteria of 30-, 60-, or 90-min plasma glucose on oral glucose tolerance test ≥200 mg/dL (≥11.1 mmol/L) and confirmatory testing in those aged ≥18 years have been used in clinical trials (84). Dysglycemia can be defined by one or more criteria.[2]
DKA, diabetic ketoacidosis; T1D, type 1 diabetes.

Teizeild was studied in the Phase II TN-10 trial[6]

TN-10: A Phase II, randomised, placebo-controlled, double-blind, time-to-event trial including 76 patients (aged 8–49 years) with Stage 2 T1D*[6]

Patients received either Teizeild or placebo once daily by intravenous infusion for 14 days.[6] Patients in the Teizeild group had a total drug exposure comparable to the total drug exposure achieved with the recommended total Teizeild dose.[1]



Primary endpoint: Time from randomisation to onset of clinical autoimmune T1D (Stage 3).[6]
Key safety measure: Number of participants with adverse reactions.[6]

Limitations: The TN-10 trial was relatively small (N=76) and therefore the estimated power was limited. The extended follow-up analyses are not included in the EMA SmPC. Definitive conclusions cannot be derived from the extended follow-up data. Patient results may vary.[6-8]

*Stage 2 T1D was defined as having two or more diabetes-related autoantibodies (including GADA, IA-2A, ICA and ZnT8A) and dysglycaemia during an OGTT.[6]

IN THE TN-10 PRIMARY ANALYSIS

Teizeild resulted in 2x more time in presymptomatic Stage 2 T1D vs placebo*[6]

The primary endpoint was met, giving patients more time without clinical disease (Stage 3).*[6]

Primary endpoint: Median time from randomisation to Stage 3 T1D onset.[6]

Median time to Stage 3 T1D onset[6]:

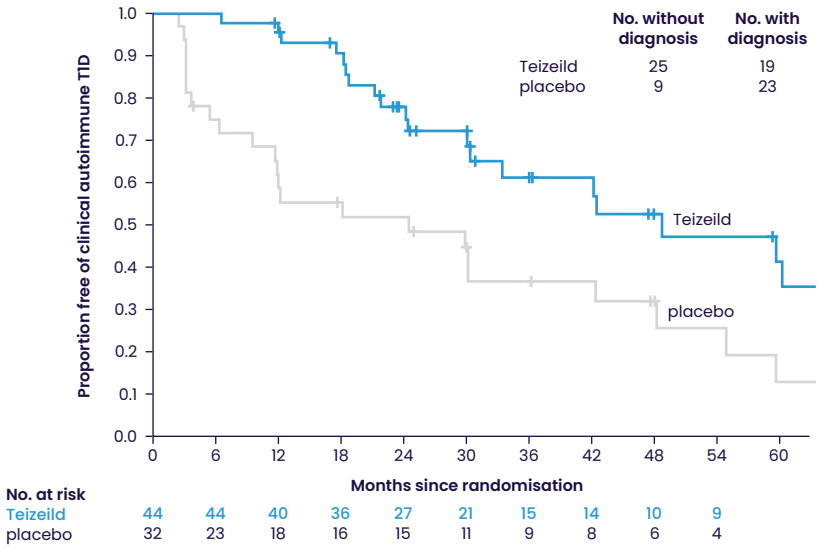
~4 years (48.4 months) with Teizeild (n=44)

~2 years (24.4 months) with placebo (n=32)

2 more years clinical disease-free vs placebo[6]

Median follow-up time: ~2 years (745 days [range: 74–2,683 days]).[6]

Kaplan–Meier estimates of the proportions of patients without clinical diagnosis†[6]



HR (95% CI): 0.41 (0.22–0.78); two-sided p=0.006 by adjusted Cox proportional-hazards model.[6]

Extracted figure from Herold KC, et al. *N Engl J Med.* 2019;381(7):603–613.

Patient results may vary.
*In the primary analysis of the TN-10 trial, 76 patients aged 8–49 years with Stage 2 T1D received either a single 14-day course of Teizeild or placebo.[6] †The numbers of participants with or without a diagnosis of clinical autoimmune T1D (upper right) represent data at the conclusion of the trial. Tick marks indicate censored data.[6]

Help delay clinical onset

IN THE FIRST TN-10 EXTENDED FOLLOW-UP

Teizeild provided almost 3 more years in presymptomatic Stage 2 T1D vs placebo[7]

Primary endpoint: Median time from randomisation to Stage 3 T1D onset.[7]
Median follow-up time: ~2.5 years (923 days [range: 74–3,119 days]).[7]

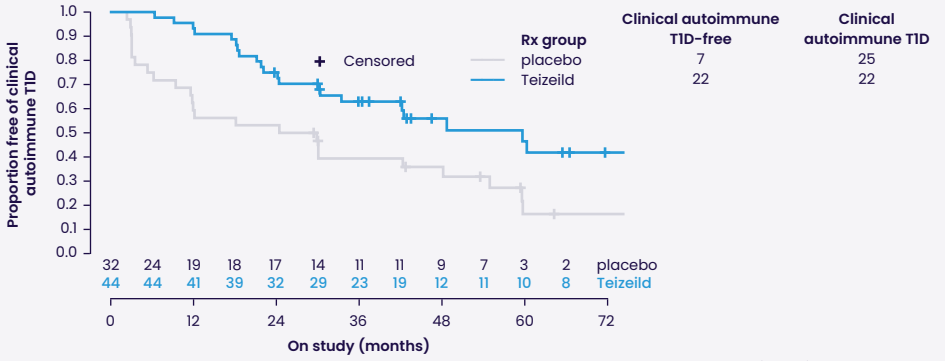
Median time to Stage 3 T1D onset[7]:

~5 years (59.6 months) with Teizeild (n=44)

~2 years (27.1 months) with placebo (n=32)

Almost **3 more years** (2.7 years) **without clinical disease** vs placebo[7]
HR: 0.46; p=0.01 by adjusted Cox proportional-hazards model[7]

Kaplan–Meier estimates of the proportions of patients without clinical diagnosis[7]



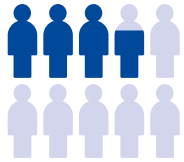
HR: 0.46; p=0.01 by adjusted Cox proportional-hazards model.[7]

Extracted figure from Sims EK, et al. *Sci Transl Med.* 2021;13(583):eabc8980.

At the end of this extended follow-up, 50% (n=22/44) of Teizeild-treated patients had not progressed to Stage 3 T1D vs 22% (n=7/32) of placebo-treated patients.[7]

IN THE SECOND TN-10 EXTENDED FOLLOW-UP

After a median follow-up of ~7 years (80 months): the median time to Stage 3T1D was **~4 years** in the Teizeild group vs **~2 years** in the placebo group p=0.0026.*[8]



36.4% of Teizeild-treated patients (n=16/44) had not progressed to Stage 3 T1D vs 12.5% (n=4/32) with placebo (p=0.03; Fisher's exact test)[8]

Visual created from publication data. Lledó-Delgado A, et al. *J Clin Invest.* 2024;134(18):e177492.

Patient results may vary.
*At the end of the second extended follow-up analysis of the TN-10 trial, the median time to Stage 3 T1D onset was ~4 years (52.2 months [95% CI: 30.5–86.7]) in the Teizeild group vs ~2 years (27.3 months [95% CI: 9.5–48.4]) in the placebo group.[8]

Not actual patient.

Teizeild is an immunomodulator with a well-documented safety profile[1]

The safety of Teizeild has been assessed*:

in over 1,000 patients with Stage 2 T1D or from an unapproved population[1,9]

across seven clinical trials including patients aged ≥8 years[1,9]

The most frequently reported adverse reactions with Teizeild were[1]:

- lymphopenia (75%)
- leukopenia (58%)
- neutropenia (37%)
- rash (36%)

Serious adverse reactions in Teizeild-treated patients included[1]:

- CRS (0.9%)
- increased ALT (0.2%)
- increased AST (0.2%)
- severe lymphopenia (0.2%)
- neutropenia (0.2%)
- infection (0.2%)

The majority of adverse reactions[9]:
- were mechanism of action-based and predictable
- had transient effects

Teizeild should be administered by an HCP with access to appropriate medical support to manage potential severe adverse reactions.[1]

This medicinal product is subject to risk minimisation measures. Please refer to the SmPC and the Guide for Healthcare Professionals for more information.

*The safety of Teizeild was evaluated in an integrated analysis of seven clinical trials including patients with Stage 2 T1D (TN-10) and patients from an unapproved population. The analysis included a total of 1,346 patients, with 1,008 patients treated with Teizeild (one or two courses over a 6-, 12-, or 14-day dosing period, separated by 6 or 12 months) and 356 in the control group (placebo or standard of care). The mean (SD) age in the pooled analysis was 16.3 years (7.0) in the Teizeild group and 15.4 years (7.0) in the control group.[9]

Well-documented safety profile

CRS, lymphopenia and serious infections are possible serious adverse reactions with Teizeild[1]

CRS

In the TN-10 trial, CRS occurred in **2% of Teizeild-treated patients**.[1]

In a pooled safety analysis of seven clinical trials[1]:

- **6% of Teizeild-treated patients developed CRS**, with 14% of these cases reported as serious
- symptoms of CRS, such as fever and fatigue, typically occurred during the first five days of treatment, with cases observed through 28 days after the last administration

Liver enzyme and bilirubin elevations[1]

- Liver enzyme and bilirubin elevations were observed in Teizeild-treated patients, both in the context of CRS and in patients without CRS
- Liver transaminase elevations were observed more frequently in patients treated with Teizeild who experienced CRS[1]
- On laboratory analysis, 7.8% of Teizeild-treated patients experienced a peak ALT >3x ULN and 5.3% of Teizeild-treated patients experienced a peak AST >3x ULN
- Most liver enzyme elevations were **transient** and **resolved 1–2 weeks** after treatment

Lymphopenia

In the TN-10 trial[1]:

- lymphopenia was reported in **73% of Teizeild-treated patients**
- the average lymphocyte count nadir occurred at Day 5 of treatment, with recovery and return to baseline by Week 6

In the pooled safety analysis[1]:

- the majority (75%) of Teizeild-treated patients developed lymphopenia
- for most patients who developed lymphopenia, lymphocyte levels began to recover after the fifth day of treatment and **returned to pre-treatment values within two weeks after treatment completion and without dose interruption**
- severe lymphopenia (<0.5 x 10^9 cells/L) lasting one week or longer occurred in 2% of Teizeild-treated patients and 0.5% of patients permanently discontinued treatment because of lymphopenia

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CRS, lymphopenia and serious infections are possible serious adverse reactions with Teizeild[1]

Serious infections

In the TN-10 trial:

- serious infections (cellulitis, gastroenteritis, pneumonia, wound infection) were reported in **9% of Teizeild-treated patients**[1]

In the pooled safety analysis:

- serious infections were reported in **3% of Teizeild-treated patients**, including gastroenteritis, cellulitis, pneumonia, abscess, sepsis and infectious mononucleosis[1]

Teizeild should be administered by an HCP with access to appropriate medical support to manage potential severe adverse reactions.[1]

To manage serious adverse reactions[1]:

For CRS:

- **How to premedicate:** Premedicate for the first five days of 14-day treatment course with: (1) an NSAID or acetaminophen, (2) an antihistamine, and/or (3) an antiemetic[1]
- **Monitoring:** Monitor liver enzymes and bilirubin during treatment, more frequently within the first week. Discontinue treatment in patients who develop elevated ALT or AST >5x the upper limit of normal, or bilirubin >3x the upper limit of normal[1]
- **Treatment:** Treat symptoms of CRS with antipyretics, antihistamines and/or antiemetics[1]
- **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). If CRS does not improve or recurs despite the pause, discontinuing treatment may be warranted[1]

For lymphopenia:

- **monitor white blood cell counts** during the treatment period[1]
- if **prolonged severe lymphopenia** (<0.5 x 10^9 cells/L lasting one week or longer) develops, treatment should be **permanently discontinued**[1]

For serious infections:

- Teizeild is not recommended in patients with **active serious infection or chronic infection** other than localised skin infections[1]
- **monitor patients for signs and symptoms of infection** during and after the treatment period[1]
- if serious infection develops, appropriate treatment should be provided and **Teizeild should be permanently discontinued**[1]

Please refer to the SmPC and the Guide for Healthcare Professionals for more information. You will also find guidance for vaccination prior to or after treatment.

ALT, alanine aminotransferase; AST, aspartate aminotransferase; CD3, cluster of differentiation 3; CRS, cytokine release syndrome; NSAID, nonsteroidal anti-inflammatory drug; T1D, type 1 diabetes; TN-10, TrialNet-10.

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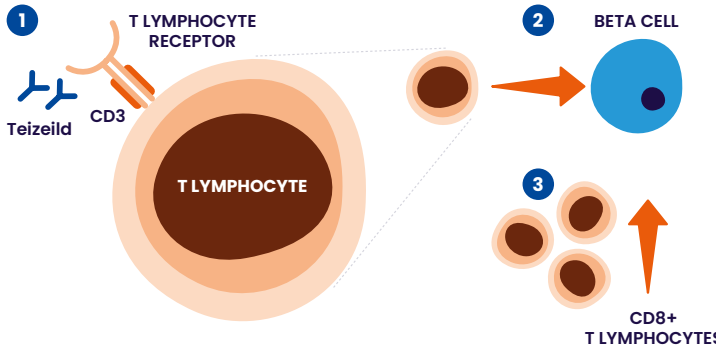
Teizeild was designed to modulate the autoimmune process involved in the destruction of pancreatic beta cells[1,2]



1. **Teizeild binds to CD3 antigens** on the surface of T lymphocytes[1,2]

2. Through modulation of T lymphocyte signalling by Teizeild, **autoreactive CD8+ T lymphocytes** that act on pancreatic beta cells **may become partially exhausted and deactivated**[1,2,8]

3. This treatment may result in an increased proportion of **CD8+ T lymphocytes with signs of exhaustion** in the peripheral blood[1,8]

Dosing Information

Dosing[1]

Teizeild should be administered by intravenous infusion (over a minimum of 30 minutes), using a body surface area (BSA)-based dosing, once daily for 14 consecutive days.

Recommended dosing schedule

Day	1	2	3	4	5–14
Dose (µg/m²)	65	125	250	500	1,030

For the first 5 days of dosing, **premedicate prior to Teizeild infusion** with: (1) an **NSAID** or **paracetamol**, (2) an **antihistamine** and (3) use of an **antiemetic** could be considered. **Additional doses** of premedication should be administered **if needed.**

Additional dosing information[1]

Pharmaceutical form and concentration
- Clear, colourless concentrate for solution for infusion
- 1 mL of concentrate contains 1 mg of Teizeild
- Each vial contains 2 mg of Teizeild in 2 mL of concentrate (2 mg/2 mL)

Do not administer two doses on the same day

If an infusion is missed
Resume dosing by administering all remaining doses on consecutive days to complete the course

Infusion should be completed within 6 hours of the start of preparation[1]
Discard the infusion solution if not administered within 6 hours of preparation[1]

Laboratory evaluation and vaccinations prior to treatment[1]

Prior to initiation of Teizeild, there are a number of laboratory evaluations required to ensure that Teizeild is suitable for patients. All age-appropriate vaccinations must also be administered before treatment

- Prior to initiating Teizeild obtain a complete blood count and liver enzyme tests
- Administer all age-appropriate vaccinations prior to starting Teizeild:
  – Administer live-attenuated (live) vaccines at least 8 weeks prior to treatment
  – Administer inactivated (killed) vaccines or mRNA vaccines at least 2 weeks prior to treatment

Use of Teizeild is not recommended in patients with:
- Lymphocyte count <10^9 lymphocytes/L
- Haemoglobin <100 g/L
- Platelet count <150 x 10^9 platelets/L
- Absolute neutrophil count <1.4 x 10^9 neutrophils/L
- Elevated ALT or AST >2 x ULN or bilirubin >1.5 x ULN
- Laboratory or clinical evidence of acute infection with Epstein-Barr virus (EBV) or cytomegalovirus (CMV)
- Active serious infection or chronic active infection other than localised skin infections

Abbreviations

ALT, alanine aminotransferase; AST, aspartate transaminase; CD3, cluster of differentiation 3; CD8, cluster of differentiation 8; CI, confidence interval; CRS, cytokine release syndrome; EMA, European Medicines Agency; GADA, glutamic acid decarboxylase 65 autoantibody; HCP, healthcare professional; HR, hazard ratio; IA-2A, insulinoma-associated antigen 2 autoantibody; ICA, islet cell autoantibody; NSAID, nonsteroidal anti-inflammatory drug; OGTT, oral glucose tolerance test; Rx, medical prescription; SD, standard deviation; SmPC, Summary of Product Characteristics; T1D, type 1 diabetes; TN-10, TrialNet-10; ULN, upper limit of normal; ZnT8A, zinc transporter-8 autoantibody.

References

1. Teizeild (teplizumab) Summary of Product Characteristics.
2. Herold KC, Delong T, Perdigoto AL, et al. *Nat Rev Immunol*. 2024;24(6):435-451.
3. Subramanian S, Khan F, Hirsch IB. *BMJ*. 2024;384:e075681.
4. Nagy G, Szekely TE, Somogyi A, et al. *World J Diabetes*. 2022;13(10):835-850.
5. Sims EK, Besser REJ, Dayan C, et al. *Diabetes*. 2022;71(4):610-623.
6. Herold KC, Bundy BN, Long SA, et al. *N Engl J Med*. 2019;381(7):603-613.
7. Sims EK, Bundy B, Stier K, et al. *Sci Transl Med*. 2021;13(583):eabc8980.
8. Lledó-Delgado A, Preston-Hurlburt P, Currie S, et al. *J Clin Invest*. 2024;134(18):e177492.
9. Dayan C, Herold KC, Simmons KM, et al. *Diabetologia*. 2024;67(Suppl 1):1-593.

For further guidance on dosing, please refer to the Summary of Product Characteristics for Teizeild, which can be accessed here

Abbreviated Summary of Product Characteristics

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 of the full SmPC for how to report adverse reactions.

Teizeild® (teplizumab), 1 mg/ml concentrate for solution for infusion

Indication: Teizeild is indicated to delay the onset of stage 3 type 1 diabetes (T1D) in adult and paediatric patients 8 years of age and older with stage 2 T1D. **Posology and method of administration*:** Laboratory evaluation and vaccination prior to initiation: Teizeild should be administered by a healthcare professional with access to appropriate medical support to manage potential severe adverse reactions. Prior to initiating Teizeild, a complete blood count and liver enzyme tests should be obtained. Use of Teizeild is not recommended in patients with: Lymphocyte count less than 1.0 x 10^9 lymphocytes/l, haemoglobin less than 100 g/l, platelet count less than 100 × 10^9 platelets/l, absolute neutrophil count less than 1.5 × 10^9 neutrophils/l, elevated alanine aminotransferase (ALT) or aspartate aminotransferase (AST) greater than 2 times the upper limit of normal (ULN) or bilirubin greater than 1.5 times ULN, laboratory or clinical evidence of acute infection with Epstein-Barr virus (EBV) or cytomegalovirus (CMV), active serious infection or chronic active infection other than localised skin infections. Furthermore, all age-appropriate vaccinations should be administered prior to initiating Teizeild. Premedication: Premedication should be used prior to Teizeild infusion for the first 5 days of dosing with: (1) a nonsteroidal anti-inflammatory drug (NSAID) or paracetamol, (2) an antihistamine, and (3) use of an antiemetic could be considered. Additional doses of premedication should be administered if needed. Posology: Teizeild should be administered by intravenous infusion (over a minimum of 30 minutes), using body surface area (BSA)-based dosing, once daily for 14 consecutive days as follows: Day 1: 65 micrograms/m², Day 2: 125 micrograms/m², Day 3: 250 micrograms/m², Day 4: 500 micrograms/m², Days 5 through 14: 1 030 micrograms/m². Missed dose(s): If a planned Teizeild infusion is missed, dosing should be resumed by administering all remaining doses on consecutive days to complete the 14-day treatment course. Treatment discontinuation: Temporary treatment discontinuation may be required according to the severity of laboratory abnormalities. Dose interruption should not exceed 3 days. For temporary and permanent discontinuation see section 4.2 of the Summary of Product Characteristics. **Contraindications*:** Hypersensitivity to the active substance or to any of the excipients. **Warnings and precautions*:** Cytokine release syndrome (CRS): CRS has been observed in clinical studies in patients treated with teplizumab during the treatment period and through 28 days after the last administration. CRS symptoms included fever, nausea, fatigue, headache, myalgia, arthralgia, increased ALT, increased AST, and increased total bilirubin. These symptoms typically occurred during the first 5 days of treatment. To mitigate CRS: 1. antipyretics, antihistamines and/or antiemetics should be administered prior to treatment. 2. liver enzymes and bilirubin should be monitored during treatment, more frequently within the first week. Treatment should be discontinued in patients who develop ALT or AST greater than 5 times the upper limit of normal (ULN) or bilirubin greater than 3 times ULN. 3. Symptoms of CRS should be treated with antipyretics, antihistamines and/or antiemetics. If severe CRS develops, temporarily pausing dosing for 1-2 days should be considered (and the remaining doses to complete the full 14-day course should be administered on consecutive days). If CRS does not improve or if CRS recurs despite the pause, discontinuing treatment may be warranted. Serious infections: Bacterial and viral infections have occurred in patients treated with Teizeild, including gastroenteritis, cellulitis, pneumonia, abscess, sepsis. Use of Teizeild is not recommended in patients with active serious infection or chronic infection other than localised skin infections. Patients should be monitored for signs and symptoms of infection during and after treatment. If serious infection develops, appropriate treatment should be provided and Teizeild should be discontinued. Lymphopenia: 75% of patients treated with Teizeild in clinical studies developed lymphopenia. For most patients who experienced lymphopenia, lymphocyte levels began to recover after the fifth day of treatment and returned to pre-treatment values within two weeks after treatment completion and without dose interruption. White blood cell counts should be monitored during the treatment period. If prolonged severe lymphopenia (< 0.5 × 10^9 cells/l lasting 1 week or longer) develops, treatment should be discontinued. Hypersensitivity reactions: Acute hypersensitivity reactions including serum sickness, angioedema, urticaria, rash, vomiting and bronchospasm occurred in patients treated with Teizeild. Generalised cutaneous reactions and anaphylaxis have occurred in at least one patient. If severe hypersensitivity reactions occur, Teizeild should be discontinued and treatment should be provided promptly. Vaccinations: The safety of immunisation with live-attenuated vaccines in patients treated with Teizeild has not been studied. Additionally, Teizeild may interfere with the immune response to vaccination and decrease vaccine efficacy. (1) All age-appropriate vaccinations should be administered prior to starting Teizeild. (2) Inactivated or mRNA vaccinations are not recommended within the 2 weeks prior to treatment, during treatment, or up to 6 weeks after completion of treatment. (3) Live-attenuated vaccinations are not recommended within the 8 weeks prior to starting treatment, during treatment, or up to 52 weeks after completion of treatment. Glucose monitoring: Blood glucose as well as signs and symptoms of hypoglycaemia or hyperglycaemia should be monitored and diabetes managed according to current practice guidelines. Patients must not have type 2 diabetes (T2D) or secondary dysglycaemia related to a condition other than T1D (e.g. diabetes secondary to medicinal products or surgery, monogenic diabetes). Excipients: This medicinal product contains less than 1 mmol (23 mg) sodium per vial, that is to say essentially 'sodium-free'. Teizeild is administered in 0.9% sodium chloride intravenous solution. This medicinal product contains 0.10 mg of polysorbate 80 in each vial. Polysorbates may cause allergic reactions. For further details on special warnings and precautions for use see full SmPC.

Interactions*: No drug interaction studies have been performed. Teizeild should be administered with caution in patients with concomitant medicinal products that are associated with significant liver abnormalities, cytopenias and other immune modulators. Cytokine release syndrome accompanied by a slight and transient increase in IL-6 concentrations may occur with Teizeild. Teizeild is not expected to have any relevant cytochrome P450 mediated drug–drug interactions. Teizeild may interfere with the immune response to vaccination. **Fertility, pregnancy and lactation*:** Women of childbearing potential have to use effective contraception during treatment with teplizumab and for 30 days after the last dose of treatment. Teizeild is not recommended during pregnancy. Breast-feeding should be discontinued during treatment with Teizeild and for 30 days after the last dose of treatment. There are no clinical data available for teplizumab on the effects on fertility. **Effects on ability to drive and use machines:** Teizeild has a minor influence on the ability to drive and use machines. Fatigue has been reported. Undesirable effects*: Very common: Lymphopenia, thrombocytopenia, leukopenia, neutropenia, haemoglobin decreased, headache, vomiting, nausea, alanine aminotransferase increased, aspartate aminotransferase increased, rash, pruritus, pyrexia, fatigue. Common: Eosinophilia, cytokine release syndrome, diarrhoea, abdominal pain, bilirubin increased, rash maculo-papular, rash pruritic, urticaria, skin exfoliation, chills. Uncommon: Infections, hypersensitivity. Not known: Epstein-Barr virus reactivation, pain, illness.

Sections marked with * are rewritten/abbreviated compared to the approved Summary of Product Characteristics. Detailed information on this medicinal product is available on the website of the European Medicines Agency https://www.ema.europa.eu

Marketing Authorization Holder: Sanofi Winthrop Industrie, 82 avenue Raspail, 94250 Gentilly, France.

Belgium: Prescription only. Date of last update: 03/2026.

Denmark: Pack sizes: 1 vial of 2 ml (Vnr 425303). **Price** (AIP): DKK 83,418.00/vial. **Dispensing group:** Prescription required (BEGR). **Reimbursement:** Not reimbursable. **The Summary of Product Characteristics can be obtained free of charge from Sanofi A/S, Lyngbyvej 2, 2100 Copenhagen Ø.** Version: 1

Finland: Prescription only. Local representative: Sanofi Oy, www.sanofi.fi. Date of last update: 03/2026

Netherlands: Prescription only. Date of last update: 03/2026. Reimbursement information: Not yet reimbursed.

Norway: Reseptgruppe: C. Pakninger og priser: 2 ml(hettegl.) kr 16749,80. Refusjon: H-resept: A10X X01. Lokal representant: sanofi-aventis Norge AS, Prof. Kohts vei 5-17, 1325 Lysaker. Tlf: +47 67 10 71 00. Fullstendig preparatomtale finnes på www.legemiddelsok.no/.

Sweden: Status of the product: Rx (prescription status) Sanofi AB, tel +46 8 634 50 00, www.sanofi.se, for questions about our medicines contactinfoavd@sanofi.com. Reimbursement status: Not reimbursed. See FASS.se for further information.

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