swissmedic

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Swissmedic, Swiss Agency for Therapeutic Products

Swiss Public Assessment Report

Teizeild

International non-proprietary name:	teplizumab
Pharmaceutical form:	concentrate for solution for infusion
Dosage strength(s):	2 mg/2 mL
Route(s) of administration:	intravenous
Marketing authorisation holder:	Sanofi-Aventis (Suisse) SA
Marketing authorisation no.:	70102
Decision and decision date:	approved on 21 May 2026

Note:

This assessment report is as adopted by Swissmedic with all information of a commercially confidential nature deleted.

SwissPARs are final documents that provide information on submissions at a particular point in time. They are not updated after publication.

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1 Terms, Definitions, Abbreviations

ADA	Anti-drug antibody
ADME	Absorption, distribution, metabolism, elimination
AE	Adverse event
AESI	Adverse event of special interest
ALT	Alanine aminotransferase
API	Active pharmaceutical ingredient
AST	Aspartate aminotransferase
ATC	Anatomical Therapeutic Chemical Classification System
AUC	Area under the plasma concentration-time curve
$AUC_{0\text{-}24h}$	Area under the plasma concentration-time curve for the 24-hour dosing interval
BSA	Body surface area
CHO	Chinese hamster ovary
CI	Confidence interval
C_{max}	Maximum observed plasma/serum concentration of drug
CRS	Cytokine Release Syndrome
CYP	Cytochrome P450
DDI	Drug-drug interaction
EMA	European Medicines Agency
ERA	Environmental risk assessment
FDA	Food and Drug Administration (USA)
GI	Gastrointestinal
GLP	Good Laboratory Practice
HC	Health Canada
HPLC	High-performance liquid chromatography
HSA	Singapore's Health Sciences Authority
IC/EC_{50}	Half-maximal inhibitory/effective concentration
ICH	International Council for Harmonisation
Ig	Immunoglobulin
INN	International non-proprietary name
ITT	Intention-to-treat
LoQ	List of Questions
MAH	Marketing authorisation holder
Max	Maximum
MHRA	Medicines & Healthcare products Regulatory Agency (UK)
Min	Minimum
MRHD	Maximum recommended human dose
N/A	Not applicable
NO(A)EL	No observed (adverse) effect level
PBPK	Physiology-based pharmacokinetics
PD	Pharmacodynamics
PIP	Paediatric investigation plan (EMA)
PK	Pharmacokinetics
PopPK	Population pharmacokinetics
PSP	Pediatric study plan (US FDA)
RMP	Risk management plan
SAE	Serious adverse event
SwissPAR	Swiss Public Assessment Report
T1D(M)	Type 1 Diabetes (Mellitus)
TCR	T cell receptor
TEAE	Treatment-emergent adverse event
TGA	Therapeutic Goods Administration (AU)

TMDD	Target-Mediated Drug Disposition
TPA	Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (SR 812.21)
TPO	Ordinance of 21 September 2018 on Therapeutic Products (SR 812.212.21)

2 Background information on the procedure

2.1 Applicant's request(s) and information regarding procedure

New active substance status
The applicant requested new active substance status for teplizumab in the above-mentioned medicinal product.

Work-sharing procedure
The applicant requested a work-sharing procedure with Australia's Therapeutic Goods Administration (TGA).
The Access NAS (new active substance) work-sharing initiative is a collaboration between regulatory authorities – specifically TGA, Health Canada (HC), Singapore's Health Sciences Authority (HSA), the UK Medicines & Healthcare products Regulatory Agency (MHRA) and Swissmedic – and the pharmaceutical industry.
The work-sharing initiative involves the coordinated assessment of NAS applications that have been filed in at least two jurisdictions.

2.2 Indication and dosage

2.2.1 Requested indication

Teizeild is a disease modifying agent that preserves beta cell function 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.
- to delay the progression of Stage 3 T1D in adult and paediatric patients 8 years of age and older recently diagnosed with Stage 3 T1D.

The applicant withdrew the indication initially requested for Teizeild to delay the progression of Stage 3 T1D in adult and paediatric patients 8 years of age and older recently diagnosed with Stage 3 T1D.

2.2.2 Approved 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.

2.2.3 Requested dosage

Summary of the requested standard dosage:
Teizeild is administered by intravenous infusion over a minimum of 30 minutes. Do not administer two doses on the same day

Patients with Stage 2 T1D
Body surface area (BSA)-based dosing, once daily for 14 consecutive days as follows:
- Day 1: 65 mcg/m^2
- Day 2: 125 mcg/m^2

- Day 3: 250 mcg/m^2
- Day 4: 500 mcg/m^2
- Days 5 through 14: 1,030 mcg/m^2

The requested standard dosage for the withdrawn indication is not listed.

2.2.4 Approved dosage

(see appendix)

2.3 Regulatory history (milestones)

Application	3 February 2025
Formal control completed	28 February 2025
List of Questions (LoQ)	30 June 2025
Response to LoQ	25 September 2025
2nd List of Questions (LoQ)	25 October 2025
Response to 2nd LoQ	18 December 2025
Preliminary decision	26 February 2026
Response to preliminary decision	29 March 2026
Labelling corrections and/or other aspects	5 May 2026
Response to labelling corrections and/or other aspects	11 May 2026
Final decision	21 May 2026
Decision	approval

3 Medical context

Type 1 diabetes mellitus (T1DM) is a severe disease caused by an autoimmune process that targets insulin-secreting β-cells in the pancreas, leading to their destruction. The present standard therapy consists of the administration of exogenous insulin. Potential alternative treatment strategies, so-called disease-modifying therapies, aim to suppress islet autoimmunity and thus halt the progression to clinically manifest T1DM.

Teplizumab, a recombinant humanised monoclonal antibody against the CD3ε chain of the T cell receptor (TCR)-complex on human T lymphocytes, is thought to provide a useful tool to downregulate islet autoimmunity and thus prevent or delay the onset of T1DM in patients who have been detected with islet autoantibodies in an early stage of the disease.

4 Quality aspects

4.1 Drug substance

Teplizumab is a recombinant humanised monoclonal antibody (IgG1 kappa subclass) that binds with high specificity to the CD3ε chain of the T cell receptor (TCR)-complex on human T lymphocytes. The mechanism of action of teplizumab is not fully understood, but it is thought to involve partial agonistic signalling and deactivation of pancreatic beta-cell autoreactive T lymphocytes. Teplizumab is a glycoprotein (molecular weight approx. 150 kDa, including glycosylation) composed of 2 identical heavy chains and 2 identical light chains covalently linked with inter-chain disulphide bonds.
Teplizumab DS is produced in Chinese Hamster Ovary (CHO) cells using a production bioreactor. The upstream manufacturing process is followed by downstream purification using several chromatographic steps. The downstream manufacturing process also contains dedicated viral clearance steps. The cell culture and purification processes were validated and demonstrated a consistent manufacturing process that effectively reduces product- and process-related impurities. The impurity clearance validation studies are supported by the impurity levels measured in the drug substance. The characterisation of the physicochemical and biological properties of the drug substance and its impurities was performed using state-of-the-art methods.
Several changes were implemented during development of the manufacturing process for the drug substance, including changes to the manufacturing site and production scale. However, comparability studies, including batch release data, extended characterisation data, and stress stability data, demonstrated comparability between the different processes.
The characterisation of the physicochemical and biological properties of the teplizumab drug substance and its impurities were performed using state-of-the-art methods.
The specifications for release and stability of the drug substance include relevant tests and acceptance criteria, e.g. for identity, purity and impurities, quantity, and potency. Specifications are based on published limits, clinical experience, batch analysis, and stability data, and are in conformance with current compendial or regulatory guidelines.
Batch analysis data for development, clinical, and process validation batches of teplizumab drug substance were provided. All specific analytical methods are described and adequately validated.
No significant changes were observed during storage of teplizumab drug substance under the proposed storage conditions.

4.2 Drug product

Teplizumab drug product is supplied in a glass vial as a sterile solution for intravenous infusion with a concentration of 1.0 mg/mL. The drug product is formulated in an aqueous buffered solution containing sodium chloride, sodium phosphate, and polysorbate 80. All excipients are of compendial grade and commonly used for the formulation of biopharmaceuticals. None of the excipients are of animal or human origin. The primary container is a 2 mL Type I borosilicate clear glass vial with a butyl rubber stopper and an aluminium overseal with a flip-off top. All components coming into contact with the finished product comply with Ph. Eur. requirements.
Compatibility studies were conducted to establish the in-use stability of diluted drug product with the intended materials and conditions of use.
The drug product manufacturing process consists of drug substance thaw, pooling, final formulation, bioburden-reduction filtration, sterile filtration and aseptic filling, visual inspection, secondary packaging and labelling. No major changes were implemented for the drug product manufacturing process during development.
The specifications for release and stability of the drug product include relevant tests and acceptance criteria, e.g. for identity, purity and impurities, quantity, potency, appearance, pH, osmolality, visible and subvisible particles, bacterial endotoxins, and sterility. The drug product specifications comply with current compendial or regulatory guidelines.

Batch analysis data for several batches of the drug product, including development batches, clinical batches, and process validation batches, were provided. Batch release data comply with the drug product specifications valid at the time of batch release. All specific analytical methods are validated.
The teplizumab drug product is stored at 2°C to 8°C. The stability data support a shelf life of 36 months.

4.3 Quality conclusions

The manufacturing processes (drug substance and drug product) are well described and demonstrate satisfactory and consistent quality of drug substance and drug product. The shelf life of the drug substance and drug product is supported by data from recommended storage conditions and by accelerated and stress studies. Safety concerns with regard to viral and non-viral contaminants were satisfactorily addressed. The risk of adventitious agents is minimised.

5 Nonclinical aspects

Swissmedic has not assessed the primary data relating to nonclinical aspects submitted with this application and relies on the assessment of the foreign reference authority TGA (see section 2.1 Applicant’s request / Work-sharing procedure).

6 Clinical aspects

6.1 Clinical pharmacology

The PK of teplizumab was described by a three-compartment quasi steady-state target-mediated drug disposition (TMDD) model.
The effects achieved in most studies have been reached with drug material that differs from the intended commercial material. The intended commercial material has been shown to have a lower exposure (48.5% AUCinf ratio) than the earlier material, which was used in the pivotal study TN-10 and partially in PROTECT. The root cause of this difference has not been identified. Modelling and simulations were used to adjust the posology for stage 2 T1DM to bridge to the TN-10 exposure. The bridging gives comparable exposures to what was studied in TN-10 over the whole range of expected bodyweight and body surface area (BSA). After PK bridging, the posology using the intended commercial material is as follows: d1: 65; d2: 125; d3: 250; d4: 500; d5-14: 1030 µg/ BSA as IV infusion. This treatment course is to be repeated after 6 to 12 months.

The impact of immunogenicity on PK varied between studies, with lower and/or more variable exposures in ADA-positive subjects. Its clinical relevance is unclear.
No dedicated studies of intrinsic factor were conducted. No data are available for renal or hepatic impairment, which are unlikely to have an impact on the PK of teplizumab.
With the BSA-based posology, there was no impact of bodyweight, BSA, gender or race on the PK of teplizumab. The same posology is applicable from 8 years of age.

6.2 Dose finding and dose recommendation

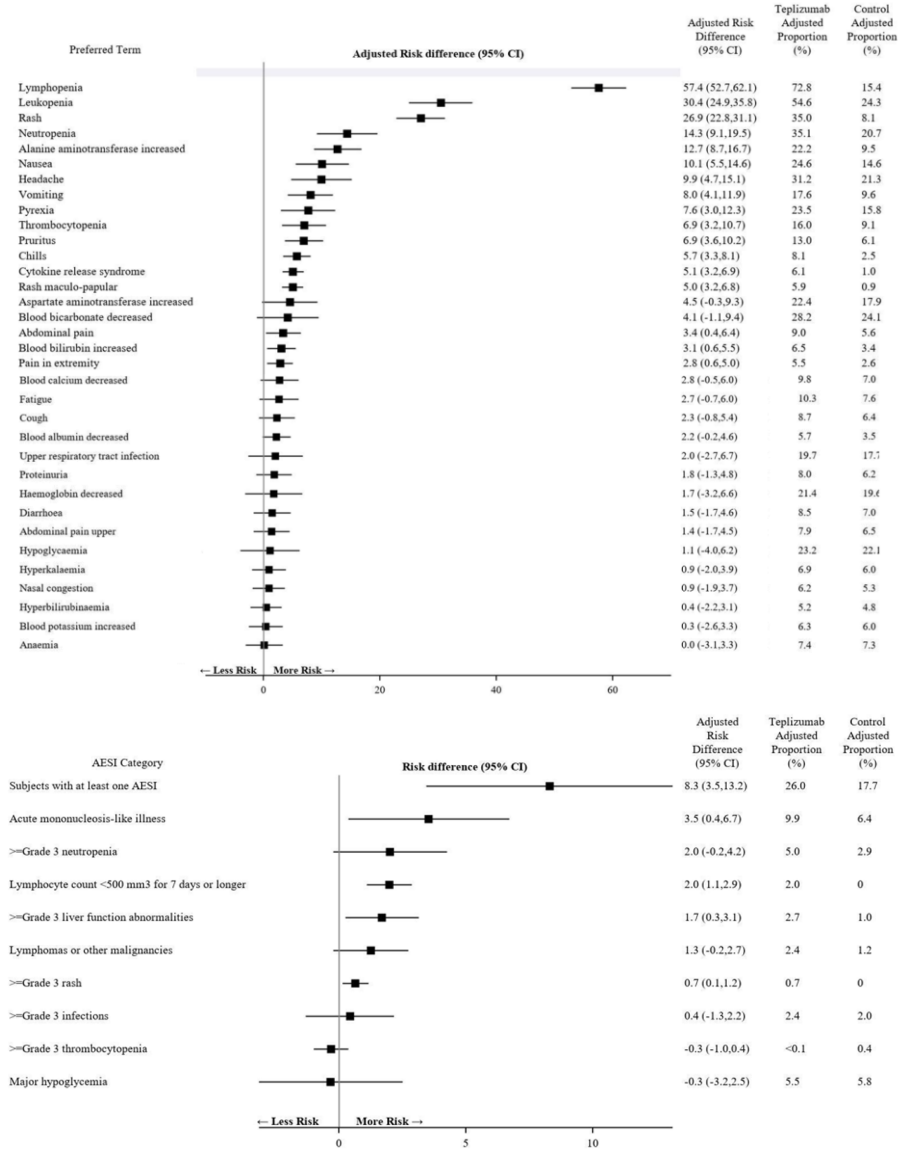
No rigorous dose finding has been performed. The dose recommendation is primarily based on the Protégé study, which demonstrated efficacy of a 14-day scheme and included an initial 4-day dose-escalation to minimise cytokine release syndrome (CRS).

6.3 Efficacy

Pivotal efficacy data came from the Phase 2 TN-10 study, a randomised placebo-controlled trial involving 76 participants with Stage 2 T1DM (i.e. detected with islet autoantibodies in an early phase of the autoimmune process without clinical symptoms). The TN-10 study demonstrated that teplizumab-treatment (single 14-day infusion course) can delay the onset of full-blown disease (stage 3 T1DM) in these patients. After a median follow-up of 80.46 months, 16 of 44 (36%) teplizumab-treated participants remained free of clinical T1DM (i.e. have not been diagnosed with stage 3 T1DM) compared with 4 of 32 (12.5%) participants in the placebo group. The median times [95% CI] to stage 3 T1DM were 52.2 months [30.5–86.9] (teplizumab) and 27.3 months [9.5–48.4] (placebo group) corresponding to about 25 months delay in progression from stage 2 to stage 3 T1DM.

6.4 Safety

TEAEs more common in teplizumab-treated participants were lymphopenia, leukopenia, neutropenia, thrombocytopenia, increased liver enzymes, decreased blood bicarbonate, rash and pruritus, and cytokine release syndrome (CRS). These were detected in the standard (MedDRA term-based) reporting of AEs (upper panel) and in the assessment of pre-specified AESIs (lower panel).



6.5 Final clinical benefit risk assessment

The clinical pharmacology of teplizumab is adequately described.

Teplizumab treatment in stage 2 T1DM is associated with a sustained effect on the progression to stage 3 T1DM (median delay ~25 months). The clinical relevance of this finding may be a prolonged metabolic stability with a beneficial impact on long-term micro- and macrovascular outcomes.

Safety concerns with teplizumab treatment include potential cytokine release syndrome, transient lymphopenia, and hypersensitivity reactions necessitating careful monitoring and considerations regarding vaccination.

The benefit-risk ratio for slowing down the progression from stage 2 to stage 3 T1DM can be considered positive.

7 Risk management plan summary

The RMP summaries contain information on the medicinal products′ safety profiles and explain the measures that are taken to further investigate and monitor the risks, as well as to prevent or minimise them.
The RMP summaries are published separately on the Swissmedic website. It is the responsibility of the marketing authorisation holder to ensure that the content of the published RMP summaries is accurate and correct. As the RMPs are international documents, their summaries might differ from the content in the Information for healthcare professionals / product information approved and published in Switzerland, e.g. by mentioning risks that occur in populations or indications not included in the Swiss authorisations.

8 Appendix

Approved Information for healthcare professionals

Please be aware that the following version of the Information for healthcare professionals for Teizeild was approved with the submission described in the SwissPAR. This Information for healthcare professionals may have been updated since the SwissPAR was published.

Please note that the valid and relevant reference document for the effective and safe use of medicinal products in Switzerland is the Information for healthcare professionals currently authorised by Swissmedic (see www.swissmedicinfo.ch).

Note:
The following Information for healthcare professionals has been translated by the MAH. It is the responsibility of the authorisation holder to ensure the translation is correct. The only binding and legally valid text is the Information for healthcare professionals approved in one of the official Swiss languages.

▼ 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 new or serious adverse reactions. See the "Undesirable effects" section for advice on the reporting of adverse reactions.

Teizeild®

Composition

Active substances

Teplizumabum.
Teplizumab is a CD3-directed monoclonal antibody (humanised IgG1 kappa) produced in Chinese hamster ovary (CHO) cells by recombinant DNA technology.

Excipients

Dinatrii phosphas (E339), Natrii dihydrogenophosphas monohydricus (E339), Polysorbatum 80, Natrii chloridum, Aqua ad iniectabile.
1 vial contains 7.45 mg of sodium.

Pharmaceutical form and active substance quantity per unit

Concentrate for solution for infusion (intravenous infusion; i.v.).
Clear, colourless solution.
Each 2 ml vial contains 2 mg teplizumab in 2 ml solution (1 mg/ml).
Dilute 2 ml teplizumab in 0.9 % sodium chloride for injection before use (see «Instructions for handling»).

Indications/Uses

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.

Dosage/Administration

To ensure traceability of biotechnological medicinal products, it is recommended that the trade name and batch number should be documented for each treatment.
Teizeild should be administered by a healthcare professional with access to appropriate medical support to manage potential severe adverse reactions.

Patient Selection

Select adult and paediatric patients 8 years of age and older for Teizeild treatment who have a diagnosis of stage 2 T1D.

Stage 2 T1D confirmed by:

- At least two positive pancreatic islet autoantibodies
- Dysglycaemia without overt hyperglycaemia

Laboratory Evaluation and Vaccination Prior to Initiation of Treatment

- Prior to initiating Teizeild a complete blood count and liver enzyme tests should be obtained.
- Administration of Teizeild is not recommended in patients with (see «Warnings and precautions»):
    - Lymphocyte count less than 1.0 x 10^9 lymphocytes/L
    - Haemoglobin less than 100 g/L
    - Platelet count less than 100 x 10^9 platelets/L
    - Absolute neutrophil count less than 1.5 x 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 the 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
- All age-appropriate vaccinations should be administered prior to starting Teizeild (see «Warnings and precautions» for detailed guidance).

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 (see «Warnings and precautions»). Additional doses of premedication should be administered if needed.

Posology

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

- Day 1: 65 micrograms/m^2
- Day 2: 125 micrograms/m^2
- Day 3: 250 micrograms/m^2
- Day 4: 500 micrograms/m^2
- Days 5 through 14: 1030 micrograms/m^2

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. Based on clinical judgment, treatment should be paused if platelet count, neutrophil count, or haemoglobin level decreases significantly.

Dose interruption should not exceed 3 days. Dosing may be resumed by administering all remaining doses on consecutive days to complete the 14-day treatment course (e.g. if dosing is missed on Days 4 and 5, dosing may restart at Day 6 with the dosing level specified for Day 4).

Treatment should be permanently discontinued if:

- Elevated liver enzymes (ALT or AST greater than 5 times ULN) or bilirubin greater than 3 times ULN
- Prolonged severe lymphopenia (< 0.5 x 10^9 lymphocytes/L lasting 1 week or longer)
- Clinically relevant (physician´s decision based on the individual patient´s data) decrease of platelet count, neutrophil count, or haemoglobin level for 3 consecutive days
- A serious infection develops

For additional information, see «Warnings and precautions» and «Undesirable effects».

Special populations

Elderly patients

Clinical studies did not include elderly patients (65 years of age and older).

Paediatric patients

The safety and efficacy of Teizeild in children younger than 8 years of age has not been established.

Hepatic impairment

No studies have been performed in patients with hepatic impairment. A change in exposure due to hepatic impairment is unlikely, but caution is advised in these patients.

Renal impairment

No studies have been performed in patients with renal impairment.

Body weight

Body surface area (BSA)-based dosing is required to normalize the exposure of Teizeild across body weight (see «Dosage/Administration»).

Method of administration

Teizeild should be administered by intravenous infusion over a minimum of 30 minutes. Two doses should not be administered on the same day.

For instructions on the preparation of Teizeild before administration, see «Instructions for handling».

Contraindications

Severe hypersensitivity (e.g., anaphylaxis) to the active substance or to any of the excipients listed in the section «Composition».

Warnings and precautions

Cytokine Release Syndrome:

Cytokine Release Syndrome (CRS) has been observed in clinical studies in patients treated with teplizumab during the treatment period and through 28 days after the last administration (see «Undesirable effects»). 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 (see «Undesirable effects»).

To mitigate CRS:

- antipyretics, antihistamines and/or antiemetics should be administered prior to Teizeild treatment (see «Dosage/Administration»).
- liver enzymes and bilirubin should be monitored during treatment, more frequently within the first week. Treatment should be discontinued in patients who develop elevated ALT or AST more than 5 times the upper limit of normal (ULN) or bilirubin more than 3 times ULN.
- 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 (see «Undesirable effects»). Epstein-Barr virus (EBV) reactivation may occur in patients treated with Teizeild. In patients with co-morbid conditions predisposing them to significant immunocompromise, clinical course of reactivation may present with

increased severity. Use of Teizeild 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. Patients should be monitored for signs and symptoms of infection during and after treatment, including viral reactivation. If serious infection develops, appropriate treatment should be provided and Teizeild should be discontinued.

Lymphopenia

In clinical trials, 75% of patients treated with teplizumab 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 (see «Undesirable effects»).

White blood cell counts should be monitored during the treatment period. If prolonged severe lymphopenia (<0.5 x 10^9 cells/L lasting 1 week or longer) develops, treatment should be discontinued (see «Undesirable effects»).

Hypersensitivity Reaction

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 (see «Undesirable effects»). If severe hypersensitivity reactions occur, treatment should be provided promptly and Teizeild should be discontinued.

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.

- All age-appropriate vaccinations should be administered prior to starting Teizeild (see «Dosage/Administration»).
- Inactivated or mRNA vaccinations are not recommended within the 2 weeks prior to treatment, during treatment, and up to 6 weeks after completion of treatment.
- Live-attenuated vaccines are not recommended ≤ 8 weeks prior to starting treatment, during treatment, and up to 52 weeks after completion of treatment.

Monitoring of glucose levels

Blood glucose as well as signs and symptoms of hypoglycaemia or hyperglycaemia should be monitored and diabetes managed according to current practice guidelines.

Other considerations

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).

Educational material/Safety guides

Healthcare professionals involved in the management of patients treated with Teizeild must be familiar with the guides available for the safe use of this medicinal product and inform patients about the potential risks associated with the use of Teizeild.

- Guide for risk minimisation for Healthcare Professional: Healthcare Professional Guide
- Guide for risk minimisation for Patients: Patient Guide – to be provided to patients by healthcare professionals

Excipients of particular interest

This medicinal product contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'. Teizeild is administered in 0.9% sodium chloride intravenous solution (see «Instructions for handling»).

Interactions

No drug interactions studies have been performed. No clinically relevant interactions are expected.

Pregnancy, lactation

Recommendations for use in women of childbearing potential

Women of childbearing potential should consider effective contraception during treatment and for 30 days after the last dose of treatment.

Pregnancy

Available case reports from clinical trials with Teizeild are insufficient to identify a drug-associated risk of major birth defects, miscarriage or other adverse maternal or foetal outcomes.

Studies in animals have demonstrated reproductive toxicity (see «Preclinical Data»).

Although there are no data on teplizumab, monoclonal antibodies can be actively transported across the placenta, and Teizeild may cause immunosuppression in the utero-exposed infant. Teplizumab is not recommended during pregnancy and for women of childbearing potential who are not using contraception.

Lactation

There are no data on the presence of teplizumab in human milk, effects on milk production, or effects on the breastfed child.

In a pre- and postnatal development toxicity study in mice, it was suggested that the surrogate antibody was present in the milk of lactating mice (see «Preclinical data»).

As endogenous maternal IgG and monoclonal antibodies are transferred into human milk, women should be advised not to breastfeed during treatment with Teizeild and for 30 days after the last dose.

Fertility

There are no clinical data available for teplizumab on the effects on fertility. Fertility and reproductive performance were unaffected in female and male mice treated with a surrogate anti-mouse CD3 antibody (see «Preclinical data»).

Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.
Fatigue has been reported in patients taking Teizeild which may have a minor influence on the ability to drive and use machines.

For other medicinal products that are administered with teplizumab, refer to the respective current product information.

Undesirable effects

Summary of the safety profile

Adverse reactions in patients treated with teplizumab were evaluated in a pool of adult and paediatric patients who participated in seven controlled clinical studies (one study in patients with Stage 2 T1D [Study TN-10], five placebo-controlled studies in patients recently diagnosed with Stage 3 T1D, one open-label standard-of-care controlled study of teplizumab in patients recently diagnosed with Stage 3 T1D).
Lymphopenia, leukopenia, neutropenia, blood bicarbonate decreased, and rash were the most frequently reported adverse reactions, which occurred at a higher frequency in the teplizumab group compared to the control group.

Tabulated list of adverse reactions

The adverse reactions occurring in ≥5% of patients in the pooled safety analysis of clinical studies or reported from post-marketing setting are shown in Table 1. The undesirable effects are presented per MedDRA System Organ Class and by frequency categories according to the following convention: “very common” (≥1/10), “common” (≥1/100, <1/10), “uncommon” (≥1/1000, <1/100), “rare” (≥1/10,000, <1/1000), “very rare” (<1/10,000), “not known” (cannot be estimated from the available data).

Table 1. Adverse reactions occurring in ≥5 % of patients in the pooled safety analysis of clinical studies or reported from post-marketing setting.

System Organ Class	Frequency Category		
	Very Common	**Common**	**Not known**
Infections and infestations			Epstein-Barr virus reactivation*
Blood and lymphatic system disorders	Lymphopenia, Leukopenia, Neutropenia, Hemoglobin decreased, Thrombocytopenia, Blood bicarbonate decreased, Blood calcium decreased.		
Immune system disorders		Cytokine release syndrome	
Nervous system disorders	Headache		
Gastrointestinal disorders	Nausea, Vomiting		Diarrhoea
Hepatobiliary disorders	Alanine aminotransferase increased, Aspartate aminotransferase increased.		
Skin and subcutaneous tissue disorders	Rash, Pruritus		Rash Pruritic, Urticaria
General disorders and administration site conditions	Pyrexia	Chills	Fatigue, Pain, Illness

* Adverse reaction from post-marketing setting.

Description of specific adverse reactions and additional information

Cytokine Release Syndrome (CRS)

In Study TN-10, CRS was reported in 2% of patients treated with teplizumab compared to 0% of patients in the placebo group.

In the pool of 7 clinical trials, 65 patients treated with teplizumab developed CRS (6% of all patients treated with Teplizumab), 14% of the CRS cases were serious adverse reactions (see «Warnings and precautions»). Liver transaminase elevations were observed more frequently in patients treated with teplizumab who experienced CRS.

Serious Infections

In Study TN-10, serious infections (cellulitis, gastroenteritis, pneumonia, wound infection) were reported in 9 % (4/44) of patients treated with teplizumab compared to 0 % (0/32) of patients treated with placebo any time during or after the first dose of study treatment.

Lymphopenia

In Study TN-10, lymphopenia was reported in 73 % of patients treated with teplizumab compared to 6 % of patients in the placebo group. The average lymphocyte count nadir occurred at Day 5 of treatment, with recovery and return to baseline by Week 6 (see «Warnings and precautions»).

Rash and Hypersensitivity Reactions

Hypersensitivity reactions were reported with teplizumab in Study TN-10. Serum sickness was observed in 2 % (1/44) of patients treated with teplizumab compared to 0 % (0/32) of patients in the placebo group. The patient who developed serum sickness had a prior history of positive anti-nuclear antibody and presented with arthralgias and elevated c-reactive protein and low C4 complement five days after completing teplizumab treatment; illness resolved in 2.5 months.

In the pool of 7 clinical trials of patients:

- Anaphylaxis (with hypoxia and bronchospasm) was observed in one patient treated with teplizumab who was hospitalised.
- Angioedema (periorbital and facial) was observed in 0.2 % of patients treated with teplizumab, compared to 0 % of patients in the control group.
- Peripheral and generalised oedema was reported in 1.2 % of patients treated with teplizumab and 0.3 % of patients in the control group.
- Rash was observed in 36 % of patients treated with teplizumab compared to 8 % of patients in the control group. The majority of events of rash observed with teplizumab treatment were not serious and resolved without intervention; although 0.3 % (2/1008) of patients treated with teplizumab had a serious rash compared to 0 % (0/356) of patients in the placebo group.
- Urticaria was reported in 2.7 % of patients treated with teplizumab and in 1.1 % of patients in the control group.

Other Adverse Reactions

Haemoglobin Decreased and Thrombocytopenia

In the pool of 7 clinical trials of patients, haemoglobin decreased was reported in 23 % of patients treated with teplizumab compared to 16 % of patients in the placebo group, and thrombocytopenia was reported in 17 % of patients treated with Teplizumab compared to 7 % of patients in the placebo group during any treatment course. Recovery occurred within 2 to 4 weeks of treatment. In clinical trials, 1.2 % of patients treated with teplizumab discontinued treatment due to haemoglobin less than 85 g/L (or a decrease of more than 20 g/L to a value less than 100 g/L), and 1 % discontinued teplizumab due to platelet count less than 50 x 10^9 platelets/L.

Liver Enzyme and Bilirubin Elevations

Liver enzyme and bilirubin elevations were observed in patients treated with Teizeild, both in the context of CRS and in patients without CRS. On laboratory analysis, 5.3% of patients treated with Teizeild experienced a peak ALT more than 3 times the ULN compared to 0.6% of patients in the control group. Most liver enzyme elevations were transient and resolved 1-2 weeks after treatment.

Immunogenicity

The observed incidence of anti-drug antibodies (ADA) is highly dependent on the sensitivity and specificity of the assay. Differences in assay methods preclude meaningful comparisons of the incidence of anti-drug antibodies in the studies described below with the incidence of anti-drug antibodies in other studies, including those of Teizeild or of other teplizumab products.

In the placebo-controlled study in patients 8 years of age and older with Stage 2 type 1 diabetes (Study TN-10) (see «Properties/effects»), approximately 57 % of patients treated with teplizumab developed anti-teplizumab antibodies, 46 % of whom developed neutralising antibodies. There was a higher incidence of rash in patients treated with Teplizumab who developed anti-teplizumab antibodies (39%) compared to those who did not develop anti-teplizumab antibodies (33 %).

Safety risks from immunogenicity are low as most of the adverse events (which are transient and manageable) appear to be related to drug treatment and not related to immunogenicity.

Based on the available data, no definitive conclusion can be made to characterise the effects of ADA on pharmacodynamics or effectiveness of Teizeild. An effect of ADAs on pharmacokinetics cannot be excluded and its clinical relevance is unknown.

Reporting suspected adverse reactions after authorisation of the medicinal product is very important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions online via the ElViS portal (Electronic Vigilance System). You can obtain information about this at www.swissmedic.ch.

Overdose

Signs and Symptoms

There is no clinical experience with overdose with teplizumab.

Management

There is no known specific antidote for Teizeild overdose. In the event of taking more than the recommended dose of Teizeild, monitor the patient for signs or symptoms of adverse effects and take all appropriate measures immediately. Clinical judgement should be applied.

Properties/Effects

ATC code

A10XX01
Pharmacotherapeutic Group: other drugs used in diabetes

Mechanism of action

Teplizumab preserves beta cell function by binding to CD3 (a cell surface antigen present on T lymphocytes) which delays the progression of T1D to stage 3 in stage 2 patients. The mechanism may involve partial agonistic signalling and deactivation of pancreatic beta cell autoreactive T lymphocytes. Teplizumab leads to an increase in the proportion of regulatory T cells and of exhausted CD8+ T cells in peripheral blood.

Pharmacodynamics

Clinical studies have shown that teplizumab binds to CD3 molecules on the surface of both CD4+ and CD8+ T cells during treatment, with internalisation of the teplizumab/CD3 complex from the surface of T cells. Pharmacodynamic effects include lymphopenia in the absence of depletion of T cells with a nadir on the 5th day of dosing, during a 14-day course of teplizumab treatment (see «Warnings and precautions»). Teplizumab exposure-response relationship and time course of pharmacodynamic response for the safety and effectiveness of teplizumab have not been fully characterised.

Clinical efficacy and safety

The effectiveness of teplizumab was investigated in the following study:

Study TN-10

A randomised, double-blind, event-driven, placebo-controlled study in 76 patients, 8 to 49 years of age with Stage 2 type 1 diabetes (T1D). Stage 2 T1D was defined as having both of the following:

1. Two or more of the following pancreatic islet autoantibodies:
    - Glutamic acid decarboxylase 65 (GAD) autoantibodies
    - Insulin autoantibody (IAA)
    - Insulinoma-associated antigen 2 autoantibody (IA-2A)
    - Zinc transporter 8 autoantibody (ZnT8A)
    - Islet cell autoantibody (ICA)
2. Dysglycaemia on oral glucose tolerance testing

In this study, patients were randomised to receive teplizumab or placebo once daily by intravenous infusion for 14 days. Patients in the teplizumab group had a total drug exposure that was comparable to the total drug exposure achieved with the recommended total teplizumab dosage (see

«Dosage/Administration»). The primary efficacy endpoint in this study was the time from randomisation to development of Stage 3 T1D diagnosis.

Baseline Patient Characteristics

In this study, 45% were female and the median age was 14 years (72 % were < 18 years old). Patients' characteristics are displayed in Table 2.

Table 2. Baseline age characteristics of adult and paediatric patients 8 years of age and older with Stage 2 Type 1 Diabetes (Study TN-10)[1]

	Teplizumab N=44	**Placebo N=32**
Age Group		
≥ 18 years	34 %	19 %
< 18 years	66 %	81 %
Paediatric Age Group Quartiles		
8 to < 11 years	21 %	25 %
11 to < 14 years	27 %	31 %
14 to < 18 years	18 %	25 %

[1] Intent to treat (ITT) population.

Baseline Disease Characteristics

Table 3 displays the baseline disease characteristics in Study TN-10.

Table 3. Baseline disease characteristics of adult and paediatric patients 8 years of age and older with Stage 2 Type 1 Diabetes (Study TN-10)[1]

	Teplizumab N=44	**Placebo N=32**
Glucose, mg/dL[2]		
median (min, max)	165 (115, 207)	154 (103, 200)
HbA1c, %		
median (min, max)	5.2 (4.6, 6.1)	5.3 (4.3, 5.6)
HLA-DR3/DR4		
Both DR3 and DR4	25 %	22 %
DR3 only	23 %	25 %
DR4 only	36 %	44 %
Missing	5 %	0
Neither DR3 nor DR4	11 %	9 %

	Teplizumab N=44	Placebo N=32
Autoantibodies Positive (N)		
1	2 %	0
2	27 %	22 %
3	25 %	16 %
4	27 %	44 %
5	18 %	19 %

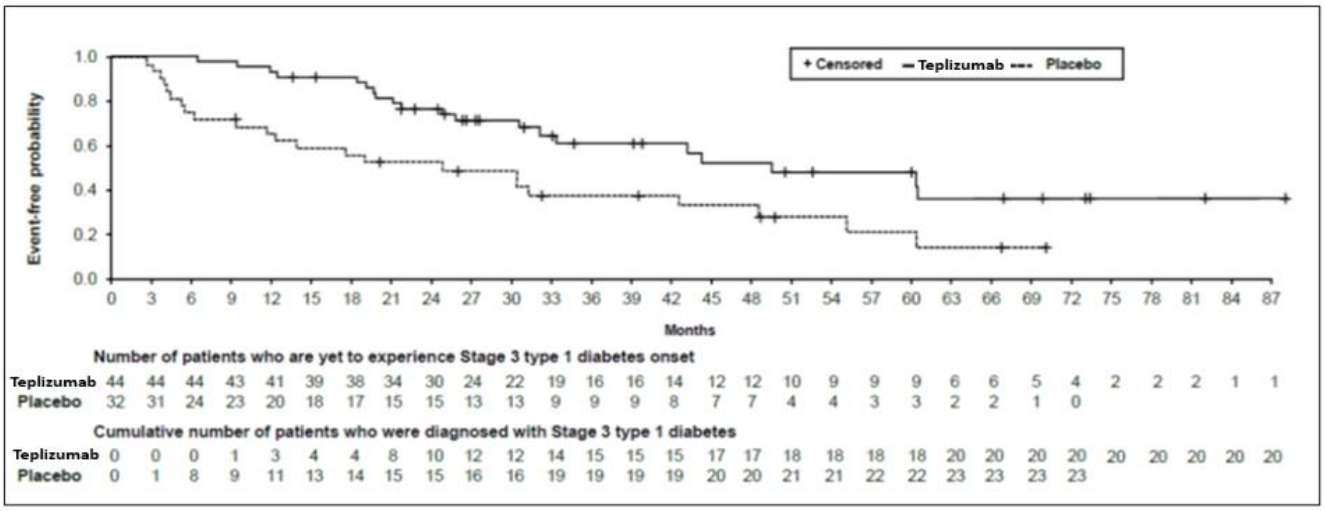
[1] Intent to treat (ITT) population [2] The glucose data are area under the time-concentration curve (AUC) values from the oral glucose tolerance test. Abbreviations: HbA1c=haemoglobin A1c, SD=standard deviation, HLA=human leukocyte antigen.

Efficacy Results

In Study TN-10, Stage 3 type 1 diabetes was diagnosed in 20 (45 %) of the patients treated with teplizumab and in 23 (72 %) of the patients treated with placebo. A Cox proportional hazards model, stratified by age and oral glucose tolerance test status at randomisation, demonstrated that the median time from randomisation to Stage 3 type 1 diabetes diagnosis was 50 months in the teplizumab group and 25 months in the placebo group, for a difference of 25 months. With a median follow-up time of 51 months, therapy with teplizumab resulted in a statistically significant delay in the development of Stage 3 type 1 diabetes, hazard ratio 0.41 (95 % CI: 0.22 to 0.78; p=0.0066) (Figure 1).

Study TN-10 was not designed to assess whether there were differences in the effectiveness between subgroups based on demographic characteristics or baseline disease characteristics.

Figure 1: Kaplan-Meier curve of time to diagnosis of Stage 3 Type 1 Diabetes in adult and paediatric patients 8 years of age and older with Stage 2 Type 1 Diabetes by treatment group (Study TN-10)[1]



[1] ITT population

In a second extended follow-up on Study TN-10, after 80.5 months of median follow-up time, 16 (36%) of the patients treated with teplizumab had not been diagnosed with stage 3 T1D compared to 4 (13%) in the placebo group.

Pharmacokinetics

Steady state concentrations of teplizumab are not expected to be achieved during the 14-day course of teplizumab.

Absorption

There is no information about absorption since teplizumab is administered intravenously.

Distribution

The central volume of distribution (Vd) of teplizumab was 2.3 L in a 60 kg subject.

Metabolism

Teplizumab is expected to be metabolised into small peptides by catabolic pathways.

Elimination

Teplizumab showed saturable binding and elimination. The population clearance of teplizumab is 2.7 L/day in a 60 kg subject.

Kinetics in specific patient groups

Age

No clinically significant differences in the pharmacokinetics of teplizumab were observed based on age (8 to 35 years old).

Gender

No clinically significant differences in the pharmacokinetics of teplizumab were observed based on biologic sex.

Race

No clinically significant differences in the pharmacokinetics of teplizumab were observed based on racial groups (White, Asian).

Weight

BSA-based dosing normalises the exposure to teplizumab across body weight.

Paediatric patients

No clinically significant differences in the pharmacokinetics of teplizumab were observed in paediatric patients 8 years of age and older.

Hepatic impairment

Specific studies to evaluate the pharmacokinetics of teplizumab in patients with hepatic impairment have not been performed.

Renal impairment

Specific studies to evaluate the pharmacokinetics of teplizumab in patients with renal impairment have not been performed.

Preclinical data

Genotoxicity, mutagenicity and carcinogenicity

No studies have been performed to assess the genotoxic, including mutagenic, potential of teplizumab. As an antibody, teplizumab is not expected to interact directly with DNA. No long-term studies have been performed to assess the carcinogenic potential of teplizumab.

Reproductive toxicity

In an embryo-foetal developmental toxicity study, pregnant mice were administered a murine surrogate anti-mouse CD3 antibody by subcutaneous injection at dose levels of 0, 0.03, 0.3, or 20 mg/kg on gestation days 6, 10, and 14. Increase in post-implantation loss occurred in the 20 mg/kg group, in the presence of maternal toxicity.

In a pre- and postnatal development toxicity study in pregnant mice, in which the murine surrogate antibody was administered every 3 days from gestation day 6 through lactation day 19 at doses of 0, 0.3, 3, or 20 mg/kg, no maternal toxicity or increased incidence of post-implantation loss was observed. Reductions in T cell populations and increases in B cells, and a reduction in the adaptive immune response to keyhole limpet hemocyanin (KLH) were observed in the offspring on postnatal days 35 and 84 at 20 mg/kg. The surrogate antibody was present in the offspring serum at level less than 1.5 % that of maternal serum at the high dose. A trend towards reduction in fertility was observed in the offspring of dams administered the murine surrogate antibody at 20 mg/kg.

Fertility and reproductive performance were unaffected in female and male mice that received a murine surrogate anti-mouse CD3 antibody administered by the subcutaneous route at doses up to 20 mg/kg.

Other information

Incompatibilities

In the absence of compatibility studies, Teizeild must 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 «Dosage/Administration» and «Instructions for handling».

Incompatible materials:

- Ethylene-propylene copolymer (EPC), polypropylene (PP), polyethylene (PE), and polyolefin (PO) blend infusion bags
- Light protected infusion sets
- For Teizeild dose <120 micrograms: ethylene vinyl acetate (EVA) bags.

Shelf life

Unopened Vial

3 years

Do not use this medicine after the expiry date marked as "EXP" on the pack.

After dilution

IV infusion bags

Chemical, physical and microbial in-use stability has been demonstrated for 6 hours at ambient temperature (15 °C to 25 °C).
From a microbiological point of view, it is recommended that the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should not be longer than 6 hours at ambient temperature (15 °C to 25 °C).

Syringe-based infusions

Chemical, physical and microbial in-use stability has been demonstrated for 12 hours under refrigerated conditions (2 °C to 8 °C), followed by no more than 6 hours at ambient temperature (15 °C to 25 °C).
From a microbiological point of view, it is recommended that the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should not be longer than 12 hours under refrigerated conditions (2 °C to 8 °C), followed by no more than 6 hours at ambient temperature (15 °C to 25 °C).

Special precautions for storage

Store in the refrigerator (2°C - 8°C).
Do not freeze or shake the vials.
Keep the vial in the outer carton in order to protect from light.
Store upright.

Store out of reach and sight of children.
For storage conditions after dilution of the medicinal product, see «Shelf life».

Instructions for handling

Preparation for intravenous administration

- Must dilute Teizeild prior to use. This requires a two-step dilution process.
- In preparation for dilution, inspect Teizeild visually before use. The supplied product is clear and colourless. Do not use Teizeild if particulate matter is seen or if there is a change in colour of the solution.
- Prepare Teizeild using aseptic technique. Each vial is intended for single dose only.

Step 1: Initial dilution (1:10)

- Prepare 18 mL of sodium chloride 9 mg/mL (0.9 %) solution for injection in a:
  - Sterile glass vial
    or
  - Polyvinylchloride (PVC) with di-(2-ethylhexyl)phthalate (DEHP) infusion bag
    or
  - Sterile syringe (polypropylene [PP], polycarbonate [PC] or glass)

Remove the cap from the vial – this is the preparation start time (see «Shelf life»).

Important:
Based on BSA dosing requirements (e.g., > 1.94 m^2), 2 Teizeild vials may be needed for days 5 through 14.

In these cases, to make sure the complete dose for each day is contained in 1 infusion bag or syringe:

- Prepare 2 dilution solutions.
- Add the cumulative volume for the calculated dose to a single infusion bag or a single syringe

- Remove 2 mL of Teizeild from the vial and slowly add to the 18 mL of sodium chloride 9 mg/mL (0.9 %) solution for injection. Mix gently by slowly swirling the vial or rocking the infusion bag or syringe. The resulting 20 mL diluted solution contains 100 micrograms (mcg)/mL of teplizumab.
- Calculate patient's BSA using the Mosteller formula before the treatment course.

  $$\textbf{BSA}\ (\textbf{m}^2) = \sqrt{(\text{Height (cm)} \times \text{Weight (kg)})/3600}$$

- Using the patient's BSA, calculate the dose based on the treatment day (see «Dosage/Administration»).

Dose (x mcg) = Daily dosage level $\left(\frac{\text{x mcg}}{\text{m}^2}\right)$ × BSA (m^2)

- Calculate the volume of 100 mcg/mL Teizeild solution (prepared in Step 1) to be further diluted in Step 2.

  Volume of initial dilution, 1:10 (mL) = $\frac{\text{Dose (x mcg)}}{100}$

Example for initial dilution volume (Step 1):

For a BSA of 1.25 m^2, the calculated dose for Day 3 is 250 mcg/m^2. The initial dilution volume is:

[(250 mcg/m^2) x (1.25 m^2)]/100 = 3.1 mL.

Step 2: Final dilution

There are two different methods for IV administration of the final dilution: infusion bag or syringe pump infusion. Use the appropriate calculation depending on the selected method.

- Method 1: Infusion bag for IV administration:
  - Using an appropriately sized syringe (e.g., 5 mL), withdraw the volume of diluted Teizeild solution required for that day's calculated dose from the 100 mcg/mL solution (see Step 1: Initial dilution, 1:10).
    Slowly add contents of the syringe containing the Teizeild dose to a PVC with DEHP infusion bag containing 25 mL sodium chloride 9 mg/mL (0.9 %) solution for injection. Gently rock the infusion bag to ensure that the solution mixes sufficiently. Do not shake.
  - Infusion administration has a minimum duration of 30 minutes. Infusion rate may be slowed for patient's tolerability.

- Method 2: Syringe (PP, PC or glass) for IV infusion via syringe pump [Teizeild concentration range 15 mcg/mL to 60 mcg/mL]:
  - Calculate the maximum volume that can be administrated for the calculated dose (based on treatment day, dose and patient BSA) using a minimum infusion concentration of 15 mcg/mL.

    $$\textbf{Volume}_{\textbf{Infusion}}\textbf{(mL)} = \frac{\text{Dose (x mcg)}}{\text{Minimum infusion concentration 15 mcg/mL}}$$

  - Calculate the volume of saline to be added to the infusion syringe:
    a) If the calculated maximum volume to be administered is ≤ 60 mL:

    $$\textbf{Volume}_{\textbf{Saline}}\textbf{(mL)} = \text{Volume}_{\text{Infusion}}\text{(mL)} - \text{Volume}_{\text{initial dilution, 1:10}}\text{ (mL)}$$

Example for final dilution:

For a BSA of 1.25 m^2, the calculated dose for Day 3 is 250 mcg/m^2. The calculated volume to be administered is:

[(250 mcg/m^2) x (1.25 m^2)]/15 = 20.8 mL

The volume of saline to be added to the infusion syringe is:
20.8 mL – 3.1 mL = 17.7 mL

b) If the calculated maximum volume to be administered exceeds 60 mL, the maximum infusion volume is capped at 60 mL.

$$\textbf{Volume}_{\textbf{Saline}}(\textbf{mL}) = 60\ \text{mL} - \text{Volume}_{\text{initial dilution, 1:10}}\ (\text{mL})$$

- Measure the appropriate volume of saline and transfer it to the infusion syringe.
- Using an appropriately sized syringe (e.g. 5 mL), withdraw the volume of diluted Teizeild solution calculated above (see volume of initial dilution, 1:10) and add it to the infusion syringe.
- Gently rock the infusion syringe to ensure that the solution mixes sufficiently. Do not shake.
- Attach infusion syringe to a syringe pump. The syringe pump should support rates as low as 1 mL/hour.
- Run infusion with syringe pump – **do not manually push the syringe**. Calculate the infusion rate (to ensure a minimum of 30 minutes). Maximum infusion rate should be 2 mL/min (maximum 120 mL/hour). The actual rate will vary based on the volume of infusion, as shown below.

$$\textbf{Infusion rate (mL/minute)} = \frac{\text{Volume}_{\text{Infusion}}(\text{mL})}{30\ \text{minutes}}$$

Example:

Infusion rate: 20.8 mL / 30 minutes = 0.7 mL/minute

- Infusion administration has a minimum duration of 30 minutes. Infusion rate may be slowed for patient's tolerability.

A summary of the calculations for the example is provided below:

Example							
Treatment Day and Dose	**BSA m^2**	**Patient Dose Teizeild (mcg)**	**Initial Dilution Volume 1:10 (mL)**	**Saline Volume (mL)**	**Infusion Volume (mL)**	**Infusion Concentration (mcg/mL)**	**Infusion Rate 30 min (mL/min)**
Day 3 250 mcg/m^2	1.25 m^2	312.5 mcg	3.1 mL	17.7 mL	20.8 mL	15 mcg/mL	0.7 mL/min

Please note:
These steps may also be followed if using a sterile glass vial for dilution preparation instead of a syringe (for IV infusion via syringe pump). An overfill should be considered as part of the calculations.

After dilution:

- Discard unused portion of remaining diluted Teizeild solution in the PVC with DEHP infusion bag, syringe or sterile glass vial, which contains the 100 µg/mL teplizumab.
- Start the Teizeild infusion immediately after dilution. If not used immediately, store the diluted solution for infusion as described in «Shelf life».

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Authorisation number

70102 (Swissmedic)

Packs

Teizeild is supplied in a 2 mL Type 1 borosilicate glass vial with a butyl rubber stopper and an aluminum seal with a coloured polypropylene flip-off cap.
Pack size: 1 vial (A) containing 2 mg/2 mL.

Marketing authorisation holder

Sanofi-aventis (schweiz) ag, 1214 Vernier/GE

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