

Summary of the Risk Management Plan (RMP) for TEIZEILD®

TEIZEILD® (TEPLIZUMAB)

Marketing Authorisation Holder : sanofi-aventis (suisse) sa

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Disclaimer:

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimize them. The RMP summary of TEIZEILD® is a concise document and does not claim to be exhaustive. As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization. Please note that the reference document which is valid and relevant for the effective and safe use of TEIZEILD® in Switzerland is the "Arzneimittelinformation/ Information sur le médicament" (see www.swissmedicinfo.ch) approved and authorized by Swissmedic. Sanofi-aventis (suisse) sa is fully responsible for the accuracy and correctness of the content of this published summary RMP of TEIZEILD®.

I. The medicine and what it is used for

Teizeild is authorized to delay the onset of stage 3 T1D in adult and paediatric patients 8 years of age and older with stage 2 T1D.

It contains Teplizumab as the active substance and it is given by IV infusion.

Further information about the evaluation of Teizeild benefits can be found in Teizeild's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage:

[Teizeild | European Medicines Agency \(EMA\)](#)

II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of Teizeild, together with measures to minimize such risks and the proposed studies for learning more about Teizeild risks, are outlined in the next sections.

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the PL and SmPC addressed to patients and HCPs;
- Important advice on the medicine's packaging;
- The authorized pack size - the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status - the way a medicine is supplied to the patient (eg, with or without prescription) can help minimize its risks.

Together, these measures constitute routine risk minimization measures.

In the case of Teizeild, these measures are supplemented with additional risk minimization measures (Educational/Safety advice tools for HCPs and patients) mentioned under relevant important risks, outlined in the next sections.

In addition to these measures, information about adverse reactions from solicited, spontaneous, and literature sources are collected continuously and regularly analyzed, including regular aggregate signalling activities, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of Teizeild is not yet available, it is listed under "missing information" outlined in the next section.

II.A List of important risks and missing information

Important risks of Teizeild are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Teizeild. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (eg, on the long-term use of the medicine).

Table 1 - List of important risks and missing information

Important identified risks	Cytokine release syndrome
	Lymphopenia
	Serious Infections
Important potential risk	Malignancies
Missing information	Long-term safety, including growth, in patients aged 8 to <18 years
	Use during pregnancy
	Use during breastfeeding

II.B Summary of important risks

Table 2 - Important identified risk with corresponding risk minimization activities and additional pharmacovigilance activities: Cytokine release syndrome

Cytokine release syndrome	
Evidence for linking the risk to the medicine	Cytokine release syndrome events, including serious, have been observed in teplizumab-treated patients in clinical trials and postmarketing settings. This risk is expected, based on the pharmacologic mode of action of teplizumab.
Risk factors and risk groups	Unknown

Cytokine release syndrome	
Risk minimization measures	<p>Routine risk minimization measures:</p> <p>Labeled in SmPC:</p> <ul style="list-style-type: none"> • Section 4.2 (Posology and method of administration) • Section 4.4 (Special warnings and precautions of use) • Section 4.8 (Undesirable effects) <p>Labeled in PL:</p> <ul style="list-style-type: none"> • Section 2 (What you need to know before you are given Teizeild) • Section 3 (How Teizeild is given) • Section 4 (Possible side effects) <p>Prescription only medicine.</p> <p>Additional risk minimization measures</p> <ul style="list-style-type: none"> • Healthcare Professional Guide • Patient guide
Additional pharmacovigilance activities	<p>Additional pharmacovigilance activities:</p> <ul style="list-style-type: none"> • GLOBAL REGISTRY study (OBS18565) • TEPLIZUMAB RMM EFFECTIVENESS SURVEY study (OBS21717) <p>See [Section II.C.2] of this summary for an overview of the post-authorization development plan.</p>

PL: Package Leaflet; RMM: Risk Minimization Measure; SmPC: Summary of Product Characteristics.

Table 3 - Important identified risk with corresponding risk minimization activities and additional pharmacovigilance activities: Lymphopenia

Lymphopenia	
Evidence for linking the risk to the medicine	<p>In clinical trials, lymphopenia was observed in the majority of teplizumab-treated patients (approximately 75%). Serious lymphopenia occurred in only 0.2% of participants in the teplizumab group. This risk is expected, based on the pharmacologic mode of action of teplizumab.</p> <p>Postmarketing data have not shown increased frequency.</p>
Risk factors and risk groups	Unknown
Risk minimization measures	<p>Routine risk minimization measures:</p> <p>Labeled in SmPC:</p> <ul style="list-style-type: none"> • Section 4.2 (Posology and method of administration) • Section 4.4 (Special warnings and precautions of use) • Section 4.8 (Undesirable effects) • Section 5 (Pharmacological properties) <p>Labeled in PL:</p> <ul style="list-style-type: none"> • Section 2 (What you need to know before you are given Teizeild) • Section 4 (Possible side effects) <p>Prescription only medicine.</p>

Lymphopenia	
	Additional risk minimization measures <ul style="list-style-type: none"> • Healthcare Professional Guide • Patient guide
Additional pharmacovigilance activities	Additional pharmacovigilance activities: <ul style="list-style-type: none"> • GLOBAL REGISTRY study (OBS18565) • TEPLIZUMAB RMM EFFECTIVENESS SURVEY study (OBS21717) See [Section II.C.2] of this summary for an overview of the post-authorization development plan.

PL: Package Leaflet; RMM: Risk Minimization Measure; SmPC: Summary of Product Characteristics.

Table 4 - Important identified risk with corresponding risk minimization activities and additional pharmacovigilance activities: Serious Infections

Serious Infections	
Evidence for linking the risk to the medicine	Individual diagnosis of serious bacterial and viral infections has occurred in teplizumab-treated patients in clinical trials and postmarketing.
Risk factors and risk groups	Unknown
Risk minimization measures	Routine risk minimization measures: Labeled in SmPC: <ul style="list-style-type: none"> • Section 4.2 (Posology and method of administration) • Section 4.4 (Special warnings and precautions of use) • Section 4.8 (Undesirable effects) Labeled in PL: <ul style="list-style-type: none"> • Section 2 (What you need to know before you are given Teizeild) • Section 4 (Possible side effects) Prescription only medicine. Additional risk minimization measures <ul style="list-style-type: none"> • Healthcare Professional Guide • Patient guide
Additional pharmacovigilance activities	Additional pharmacovigilance activities: <ul style="list-style-type: none"> • GLOBAL REGISTRY study (OBS18565) • TEPLIZUMAB RMM EFFECTIVENESS SURVEY study (OBS21717) See [Section II.C.2] of this summary for an overview of the post-authorization development plan.

PL: Package Leaflet; RMM: Risk Minimization Measure; SmPC: Summary of Product Characteristics.

Table 5 - Important potential risk with corresponding risk minimization activities and additional pharmacovigilance activities: Malignancies

Malignancies	
Evidence for linking the risk to the medicine	Three cases of malignancies were reported during clinical development. Currently, there is insufficient evidence from clinical studies and postmarketing data to establish a relationship between teplizumab and malignancies. The longest trial follow-up duration available in publication is the 7-years follow-up of the AbATE trial (n = 43), and this trial reported no malignancy among the 43 patients treated with two courses of teplizumab (given 1 year apart). Additionally, no malignancy has been reported in postmarketing to cut-off date (28-Feb-2025). ¹
Risk factors and risk groups	Risk of malignancies may increase with immunosuppression.
Risk minimization measures	Routine risk minimization measures: Labeled in SmPC: <ul style="list-style-type: none"> Section 5.3 (Preclinical safety data) Prescription only medicine. Additional risk minimization measures: None
Additional pharmacovigilance activities	Additional pharmacovigilance activities: <ul style="list-style-type: none"> GLOBAL REGISTRY study (OBS18565) See [Section II.C.2] of this summary for an overview of the post-authorization development plan.

SmPC: Summary of Product Characteristics.

Table 6 - Missing information with corresponding risk minimization activities and additional pharmacovigilance activities: Long-term safety, including growth, in patients aged 8 to <18 years

Long-term safety, including growth, in patients aged 8 to <18 years	
Risk minimization measures	Routine risk minimization measures: Prescription only medicine. Additional risk minimization measures: None
Additional pharmacovigilance activities	Additional pharmacovigilance activities: <ul style="list-style-type: none"> GLOBAL REGISTRY study (OBS18565) See [Section II.C.2] of this summary for an overview of the post-authorization development plan.

Table 7 - Missing information with corresponding risk minimization activities and additional pharmacovigilance activities: Use during pregnancy

Use during pregnancy	
Risk minimization measures	<p>Routine risk minimization measures:</p> <p>Labeled in SmPC:</p> <ul style="list-style-type: none"> • Section 4.6 (Fertility, pregnancy and lactation) • Section 5.3 (Preclinical safety data) <p>Labeled in PL:</p> <ul style="list-style-type: none"> • Section 2 (What you need to know before you are given Teizeild) <p>Prescription only medicine.</p> <p>Additional risk minimization measures:</p> <p>None</p>
Additional pharmacovigilance activities	<p>Additional pharmacovigilance activities:</p> <ul style="list-style-type: none"> • GLOBAL REGISTRY study (OBS18565) <p>See [Section II.C.2] of this summary for an overview of the post-authorization development plan.</p>

PL: Package Leaflet; SmPC: Summary of Product Characteristics.

Table 8 - Missing information with corresponding risk minimization activities and additional pharmacovigilance activities: Use during breastfeeding

Use during breastfeeding	
Risk minimization measures	<p>Routine risk minimization measures:</p> <p>Labeled in SmPC:</p> <ul style="list-style-type: none"> • Section 4.6 (Fertility, pregnancy and lactation) • Section 5.3 (Preclinical safety data) <p>Labeled in PL:</p> <p>Section 2 (What you need to know before you are given Teizeild)</p> <p>Prescription only medicine.</p> <p>Additional risk minimization measures:</p> <p>None</p>
Additional pharmacovigilance activities	<p>Additional pharmacovigilance activities:</p> <ul style="list-style-type: none"> • GLOBAL REGISTRY study (OBS18565) <p>See [Section II.C.2] of this summary for an overview of the post-authorization development plan.</p>

PL: Package Leaflet; SmPC: Summary of Product Characteristics.

II.C Post-authorization development plan

II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization of Teizeild.

II.C.2 Other studies in post-authorization development plan

Table 9 - Other studies in post-authorization development plan

GLOBAL REGISTRY study (OBS18565) (Cat. 3)

Purpose of the study:

The objective of this study in approximately 200 (150 exposed/50 control patients) is to characterise the long-term safety and effectiveness profile of teplizumab in patients with stage 2 T1D treated with teplizumab under real-world conditions in a multinational postmarketing setting.

TEPLIZUMAB RMM EFFECTIVENESS SURVEY study (OBS21717) (Cat. 3)

Purpose of the study:

To assess the effectiveness of RMMs' dissemination towards HCPs prescribing/dispensing teplizumab and patients treated with teplizumab and assess their knowledge and behaviour with respect to the RMMs for teplizumab use in Europe.

HCP: Healthcare Professional; RMM: Risk Minimization Measure; T1D: Type 1 Diabetes.

REFERENCES

1. Perdigoto AL, Preston-Hurlburt P, Clark P, Long SA, Linsley PS, Harris KM, et al. Treatment of type 1 diabetes with teplizumab: clinical and immunological follow-up after 7 years from diagnosis. *Diabetologia*. 2019 Apr;62(4):655-64.