Tezspire®

Solution for injection in pre-filled syringe
210 mg/1.19 ml (110 mg/ml)

Summary of the Risk Management Plan (RMP) for Tezspire® (tezepelumab)

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Based on EU RMP version 1.1 (DLP 11 Dec 2020)

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 minimise them.

The RMP summary of Tezspire® 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 Tezspire ® in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. AstraZeneca AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Tezspire ®.

SUMMARY OF THE RISK MANAGEMENT PLAN FOR TEZEPELUMAB

This is a summary of the risk management plan (RMP) for tezepelumab. The RMP details important risks of tezepelumab, how these risks can be minimised, and how more information will be obtained about tezepelumab's risks and uncertainties (missing information).

Tezepelumab's Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how tezepelumab should be used.

This summary of the RMP for tezepelumab should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of tezepelumab's RMP.

I.1 THE MEDICINE AND WHAT IT IS USED FOR

The proposed indication of tezepelumab is as an add-on maintenance treatment in adults with severe asthma (see SmPC for the full indication). It contains tezepelumab as the active substance and it is given/self-administered by subcutaneous injection.

I.2 RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMISE OR FURTHER CHARACTERISE THE RISKS

Important risks of tezepelumab, together with measures to minimise such risks and the proposed studies for learning more about tezepelumab's risks, are outlined below.

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

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised 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 (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed including Periodic Safety Update Report assessment 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 tezepelumab is not yet available, it is listed under 'missing information' below.

I.2.1 List of Important Risks and Missing Information

Important risks of tezepelumab are risks that need special risk management activities to further investigate or minimise 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 tezepelumab. 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).

Safety concerns described in the EU RMP:

Table I-1 List of Important Risks and Missing Information

Important identified risks	None
Important potential risks	None
Missing information	Use in pregnant and lactating women Long-term use (> 1 year)

The safety concerns for tezepelumab described in the EU RMP are applicable to the use in Switzerland.

In addition, the following **important potential risks** are applicable in Switzerland as required by Swissmedic:

- serious infections,
- parasitic and opportunistic infections,
- focal infections (e.g. osteomyelitis),
- malignancy.

I.2.2 Summary of Important Risks

Table I-2 Missing Information: Use in Pregnant and Lactating Women

Risk minimisation measures	Routine risk communication: SmPC Section Pregnancy, lactation and Package Leaflet Routine risk minimisation activities recommending specific clinical measures to address the risk: SmPC Section Pregnancy, lactation and Package Leaflet Additional risk minimisation measures: None
Additional pharmacovigilance activities	Study D5180R00010 - Database study of the use (and safety) of tezepelumab in women with severe asthma during pregnancy

SmPC, Summary of Product Characteristics.

Table I-3 Missing Information: Long-term Use (> 1 Year)

Risk minimisation measures	Routine risk communication: None Routine risk minimisation activities recommending specific clinical measures to address the risk: None Additional risk minimisation measures: None
Additional pharmacovigilance activities	Study D5180C00018 (DESTINATION) - Phase 3 safety extension study to evaluate the safety and tolerability of tezepelumab in adults and adolescents with severe uncontrolled asthma.

Table I-4 Important potential risks: serious infections, parasitic and opportunistic infections, focal infections

Risk minimisation measures	Routine risk communication: SmPC section Undesirable effects: infections; Warning and precaution: parasitic infections, serious infections. Routine risk minimisation activities recommending specific clinical measures to address the risk: None Additional risk minimisation measures: None
Additional pharmacovigilance activities	None

Table I-5 Important potential risk: malignancy

Risk minimisation measures	Routine risk communication: SmPC section Warning and precaution Routine risk minimisation activities recommending specific clinical measures to address the risk: None Additional risk minimisation measures: None
Additional pharmacovigilance activities	None

I.2.3 Post-Authorisation Development Plan

I.2.3.1 Studies Which Are Conditions of the Marketing Authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of tezepelumab.

I.2.3.2 Other Studies in Post-authorisation Development Plan

Tezepelumab Pregnancy Study (D5180R00010)

Study title: Study of the Use (and Safety) of Tezepelumab in Women with Severe Asthma During Pregnancy

Purpose of the study: The proposed study has the following objectives:

- Stage 1: To monitor the use of tezepelumab in pregnant women with severe asthma to inform the initiation of Stage 2.
- Stage 2:
  - To describe pregnancy and delivery outcomes in pregnancies among women with severe asthma exposed to tezepelumab during the first trimester and at any time during pregnancy.
  - To compare frequency of outcomes in pregnant women exposed to tezepelumab with that in those not exposed to tezepelumab.

DESTINATION - Long-term Extension Study (D5180C00018)

Study title: A Multicentre, Double-blind, Randomized, Placebo Controlled, Parallel Group, Phase 3, Safety Extension Study to Evaluate the Safety and Tolerability of Tezepelumab in Adults and Adolescents with Severe Uncontrolled Asthma

Purpose of the study: The primary objective of this long-term extension study is to evaluate the long-term safety and tolerability of 210 mg tezepelumab SC Q4W in severe asthma subjects. The secondary objective is to assess the long-term effect of 210 mg tezepelumab subcutaneously administered every 4 weeks on asthma exacerbations in adult and adolescent subjects with severe uncontrolled asthma compared with placebo.

(This study is not classified as a post-authorisation safety study.)