Summary of the risk management plan for Evusheld (tixagivemab and cilgavimab)

Introduction

This document is a summary of the risk management plan (RMP) for Evusheld (tixagivemab and cilgavimab). The RMP was created by the medicine manufacturer and is submitted to medicine regulators as part of the approval and safety monitoring processes.

The RMP details important risks of Evusheld, how these risks can be minimised, and how more information will be obtained about Evusheld's risks and uncertainties (missing information). Important new changes or changes to the current ones will be included in updates of the RMP by the medicine manufacturer.

The Evusheld data sheet and Consumer Medicine Information (CMI) give essential information for healthcare professionals and patients on how to use this medicine.

See also the European Public Assessment Report (EPAR), including the risk management plan, available on the European Medicines Agency website.

RMP Definitions

Important risks

Important risks need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely used.

Important risks are classified as identified or potential.

- Identified risks are concerns for which there is sufficient proof of a link with the use of the medicine.
- 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

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).

Activities to minimise or further characterise identified risks

Measures to minimise the identified risks for medicinal products may include:

- specific information for healthcare professionals and patients, such as warnings, precautions and advice on correct use, in the data sheet, consumer medicine information and package leaflet
- 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 (eg, 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 events is collected continuously by the company and regularly analysed, so that immediate action can be taken by the company as necessary. These measures constitute *routine pharmacovigilance activities*.

Other non-routine measures to further characterise the risks include safety and efficacy studies. The studies may be in particular risk groups or for particular safety concerns. They may also be a condition of the medicine's approval. These measures constitute *additional pharmacovigilance activities*.

Evusheld (tixagivemab and cilgavimab) RMP

The medicine and what it is used for

Evusheld contains the active substances tixagivemab and cilgavimab.

Evusheld is used for the pre-exposure prophylaxis of COVID-19 in adults and adolescents aged 12 years and older weighing at least 40 kg:

- Who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments that make it likely that they will not mount an adequate immune response to COVID-19 vaccination

  OR

- For whom vaccination with any approved COVID-19 vaccine is not recommended due to a history of severe adverse reaction (eg, severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).

Important risks, missing information and additional pharmacovigilance activities

The tables below summarise the risks for Evusheld, as described in the RMP.

- Table 1 is a list of the important risks (identified and potential) and missing information.
- Tables 2 to 5 provide risk minimisation measures and a list of additional pharmacovigilance activities.
- Table 6 summarises a planned study.

Table 1: List of important risks and missing information

Important identified risks	None
Important potential risks	Cardiac serious adverse events Antiviral resistance due to emerging variants
Missing information	Use in pregnant women Use in immunocompromised/immunosuppressed patients

Table 2: Important potential risk: Cardiac serious adverse events

Risk minimisation measures	Section 4.4 of the data sheet Consumer medicine information leaflet
Additional pharmacovigilance activities	None

Table 3: Important potential risk: Antiviral resistance due to emerging variants

Risk minimisation measures	Section 5.1 of the data sheet
Additional pharmacovigilance activities	None

Table 4: Missing information: Use in pregnant women

Risk minimisation measures	Section 4.6 of the data sheet Consumer medicine information leaflet
Additional pharmacovigilance activities	A post-authorisation observational study (D8850R00006) of women exposed to Evusheld during pregnancy

Table 5: Missing information: Use in immunocompromised/immunosuppressed patients

Risk minimisation measures	None
Additional pharmacovigilance activities	None

Studies

Table 6: Summary of planned study

Study	Purpose of study
D8850R00006	A post-authorization observational study of women exposed to Evusheld during pregnancy. The purpose of the study is to evaluate obstetric, neonatal and infant outcomes among women exposed to Evusheld during pregnancy.