[Evusheld®]

[100mg/ml tixagevimab and 100 mg/ml cilgavimab, solution for injection]

Summary of the Risk Management Plan {RMP) for [Evusheld®] (tixagevimab, cilgavimab)

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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 minimise them.
The RMP summary of "Evusheld®" 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 medicament" 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 "Evusheld®" in Switzerland is the "Arzneimittelinformation / Information sur le medicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. "Name of the marketing authorisation holder" is fully responsible for the accuracy and correctness of the content of the published summary RMP of "Evusheld®".

1. SUMMARY OF THE RISK MANAGEMENT PLAN FOR EVUSHELD (TIXAGEVIMAB AND CILGAVIMAB)

This is a summary of the RMP for EVUSHELD. The RMP details important risks of EVUSHELD, how these risks can be minimized, and how more information will be obtained about the risks and uncertainties for EVUSHELD (missing information).
EVUSHELD's Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how EVUSHELD should be used.
This summary of the RMP for EVUSHELD should be read in the context of all this information, including the assessment report of the evaluation and its plain-language summary.
Important new concerns or changes to the current ones will be included in updates of EVUSHELD's RMP.

2. THE MEDICINE AND WHAT IT IS USED FOR

EVUSHELD contains tixagevimab and cilgavimab as the active substances, and it is given by IM administration.

Pre-exposure prophylaxis
EVUSHELD (tixagevimab and cilgavimab) is indicated for pre-exposure prophylaxis of COVID-19 in adult and adolescents (12 years of age and older weighing at least 40 kg):

- unable to produce an adequate immune response to the SARS-CoV-2 vaccine and
- who are not currently infected with SARS-CoV-2 and who have not had recent contact with a person infected with SARS-CoV-2.

EVUSHELD is not approved for the treatment or post-exposure prophylaxis of COVID-19.
EVUSHELD is not intended as a substitute for vaccination against COVID-19.
EVUSHELD should be used according to official recommendations.

Decisions regarding the use of EVUSHELD for pre-exposure prophylaxis should take into consideration what is known about the characteristics of the circulating SARS-CoV-2 viruses, including regional or geographic differences, as well as available information about susceptibility to EVUSHELD (see “Properties/Effects”).

3. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMIZE OR FURTHER CHARACTERIZE THE RISKS

Important risks of EVUSHELD, together with measures to minimize such risks and the proposed studies for learning more about EVUSHELD risks, are outlined below.
Measures to minimize 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/PI addressed to patients and healthcare professionals;
- 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 to minimize its risks.

Together, these measures constitute routine risk minimization measures.
In addition to these measures, information about adverse reactions is collected continuously and analyzed, including PSUR 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 EVUSHELD is not yet available, it is listed under 'missing information' below.

3.1 List of important risks and missing information

Important risks of EVUSHELD are risks that need special risk management activities to further investigate or minimize the risk (see Table VI 1 and Table VI 2), 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 EVUSHELD. 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 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 (e.g., on the long-term use of the medicine).

Table 1 List of important risks and missing information

Important identified risks	None
Important potential risks	None
Missing Information	Use in pregnant women

3.2.1 Summary of important risks

Table 2 Missing information: Use in pregnant women

Risk minimization measures	Routine risk communication: SmPC Section 4.6, and Package Leaflet Section 2 Routine risk minimization activities recommending specific clinical measures to address the risk: None Additional risk minimization measures: None
Additional pharmacovigilance activities	A post-authorization Observational Study of Women exposed to EVUSHELD During Pregnancy See Section VI 2.3 of this summary for an overview of the post-authorization development plan.

4. Post-authorization development plan

4.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligations of EVUSHELD.

4.2 Other studies in post-authorization development plan

The use of EVUSHELD in pregnant women will be investigated in a post-authorization observational study of women exposed to EVUSHELD during pregnancy.