# SUMMARY OF RISK MANAGEMENT PLAN FOR METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA

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

Mircera summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how Mircera should be used.

This summary of the RMP for Mircera 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 Mircera RMP.

## I. THE MEDICINE AND WHAT IT IS USED FOR

Mircera is authorized for the treatment of symptomatic anemia associated with chronic kidney disease (see SmPC for the full indication). It contains methoxy polyethylene glycol-epoetin beta as the active substance and it is given by subcutaneous or intravenous route.

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

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

Important risks of Mircera, together with measures to minimize such risks and the proposed studies for learning more about Mircera 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 PL and SmPC 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 (e.g., 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 events is collected continuously and regularly analyzed, including Periodic Safety Update report (PSUR) assessment, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

## II.A LIST OF IMPORTANT RISKS AND MISSING INFORMATION

Important risks of Mircera are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely administered or taken. 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 Mircera. 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 (e.g., on the long-term use of the medicine).

| **List of important risks and missing information** | |
|---|---|
| Important identified risks | None |
| Important potential risks | Tumor growth progression |
| Missing information | None |

## II.B SUMMARY OF IMPORTANT RISKS

| **Important potential risk: Tumor growth progression** | |
|---|---|
| Evidence for linking the risk to the medicine | • Preclinical studies<br>• Clinical studies<br>• Meta-analysis of 53 clinical studies<br><br>Tumor growth promotion is considered a potential risk of the ESA class. However, there is no direct evidence of tumor growth promotion for methoxy polyethylene glycol-epoetin beta. In the meta-analysis which provides strongest evidence for ESAs to date, there is no study with methoxy polyethylene glycol-epoetin beta. |
| Risk factors and risk groups | Risk factors or risk groups have not been established for tumor growth promotion under methoxy polyethylene glycol-epoetin beta treatment. |
| Risk-minimization measures | **Routine risk-minimization measures:**<br>**Routine risk communication:**<br>SmPC section 4.4, Special warnings and precautions for use<br><br>SmPC section 5.1, Pharmacodynamic properties<br>**Routine risk minimization activities recommending specific clinical measures to address the risk:**<br>None<br>**Other risk minimization measures beyond the Product Information:**<br>Legal Status: Mircera is a prescription only medicine. |

ESA=erythropoietin stimulating agent; SmPC=Summary of Product Characeteristics.

## II.C POST-AUTHORIZATION DEVELOPMENT PLAN

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

None

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

None