Part VI: Summary of the risk management plan

Summary of risk management plan for Pemetrexed EVER Pharma 25 mg/ml concentrate for solution for infusion (Pemetrexed)

This is a summary of the risk management plan (RMP) for Pemetrexed EVER Pharma 25 mg/ml concentrate for solution for infusion. The RMP details important risks of Pemetrexed EVER Pharma 25 mg/ml concentrate for solution for infusion, how these risks can be minimised, and how more information will be obtained about Pemetrexed EVER Pharma 25 mg/ml concentrate for solution for infusion´s risks and uncertainties (missing information).

Pemetrexed EVER Pharma 25 mg/ml concentrate for solution for infusion's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Pemetrexed EVER Pharma 25 mg/ml concentrate for solution for infusion should be used.

I. The medicine and what it is used for

Pemetrexed EVER Pharma 25 mg/ml concentrate for solution for infusion is authorised for the treatment of malignant pleural mesothelioma and non-small cell lung cancer (see SmPC for the full indication).

It contains pemetrexed as the active substance and it is given by intravenous infusion.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Pemetrexed EVER Pharma 25 mg/ml concentrate for solution for infusion, together with measures to minimise such risks and the proposed studies for learning more about Pemetrexed EVER Pharma 25 mg/ml concentrate for solution for infusion´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 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 Pemetrexed EVER Pharma 25 mg/ml concentrate for solution for infusion is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Pemetrexed EVER Pharma 25 mg/ml concentrate for solution for infusion 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 Pemetrexed EVER Pharma 25 mg/ml concentrate for solution for infusion. 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	• Medication errors
Missing information	• none

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product. However, one additional risk has been defined by the applicant as there is a difference in the pharmaceutical dosage form and thereby the corresponding handling/dilution before administration of the medicinal product compared to the originator.

Medication error is a new important potential risk.

Important potential risk	
Evidence for linking the risk to the medicine	Published information of the summary of safety concern of comparable products having differences in the dosage form and handling/dilution before administration compared to the reference medicinal product.
Risk factors and risk groups	There are no specific risk factors and risk groups for a medication error.
Risk minimisation measures	Routine risk minimisation measures.

II.C Post-authorisation development plan

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

There are no studies which are conditions of the marketing authorisation or specific obligation of Pemetrexed EVER Pharma 25 mg/ml concentrate for solution for infusion.

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

There are no studies required for Pemetrexed EVER Pharma 25 mg/ml concentrate for solution for infusion.