Part VI: Summary of the risk management plan

Summary of risk management plan for Pemetrexed 10 mg/ml solution for infusion

This is a summary of the risk management plan (RMP) for Pemetrexed 10 mg/ml solution for infusion. The RMP details important risks of Pemetrexed 10 mg/ml solution for infusion, how these risks can be minimised, and how more information will be obtained about Pemetrexed 10 mg/ml solution for infusion's risks and uncertainties (missing information).

Pemetrexed summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Pemetrexed 10 mg/ml solution for infusion should be used.

I. The medicine and what it is used for

Pemetrexed 10 mg/ml solution for infusion is authorised in combination with cisplatin is indicated for the treatment of chemotherapy naïve patients with unresectable malignant pleural mesothelioma and for the first line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology (see SmPC for the full indication).

It contains Pemetrexed disodium as the active substance and it is given by intravenous infusion administration.

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

Important risks of Pemetrexed 10 mg/ml solution for infusion, together with measures to minimise such risks and the proposed studies for learning more about Pemetrexed 10 mg/ml 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, 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 Pemetrexed 10 mg/ml 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 10 mg/ml 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	▪ Non-compliance with folic acid and Vitamin B12 regimens manifested mainly as haematological and gastrointestinal (GI) toxicities ▪ Bone marrow suppression ▪ Gastrointestinal disorders ▪ Renal disorders ▪ Sepsis ▪ Bullous skin reaction including SJS and TEN ▪ Interstitial pneumonitis ▪ Radiation pneumonitis ▪ Radiation recall
Important potential risks	*None*
Missing information	*None*

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

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 10 mg/ml solution for infusion.

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

There are no studies required for Pemetrexed 10 mg/ml solution for infusion