13. Part VI: Summary of the risk management plan (RMP) Pemetrexed sodium, 100 mg, 500 mg, 1000 mg, Powder for solution for infusion and 25 mg/ml, Concentrate for solution for infusion

This is a summary of the RMP for pemetrexed sodium, 100 mg, 500 mg, 1000 mg, Powder for solution for infusion and 25 mg/ml, Concentrate for solution for infusion. The RMP details important risks of pemetrexed sodium, powder for solution for infusion and concentrate for solution for infusion how these risks can be minimized, and how more information will be obtained about pemetrexed sodium, powder for solution for infusion and concentrate for solution for infusion's risks and uncertainties (missing information).

Pemetrexed sodium powder for solution for infusion and concentrate for solution for infusion's summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals (HCPs) and patients on how pemetrexed sodium, powder for solution for infusion and concentrate for solution for infusion should be used.

Important new concerns or changes to the current ones will be included in updates of pemetrexed sodium powder for solution for infusion's and concentrate for solution for infusion's RMP.

13.1 Part VI: I. The medicine and what it is used for

Malignant pleural mesothelioma:

Pemetrexed sodium in combination with cisplatin is indicated for the treatment of chemotherapy naive patients with unresectable malignant pleural mesothelioma (MPM).

Non-small cell lung cancer:

Pemetrexed sodium in combination with cisplatin is indicated for the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) other than predominantly squamous cell histology

Pemetrexed sodium is indicated as monotherapy for the maintenance treatment of locally advanced or metastatic NSCLC other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy

Pemetrexed sodium is indicated as monotherapy for the second-line treatment of patients with locally advanced or metastatic NSCLC other than predominantly squamous cell histology.

It contains pemetrexed as the active substance and it is administered via intravenous route as powder for solution for infusion (100 mg, 500 mg, 1000 mg) and concentrate for solution for infusion (25 mg/ml)

13.2 Part VI: II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of pemetrexed sodium powder for solution for infusion and concentrate for solution for infusion together with measures to minimize such risks and the proposed studies

for learning more about pemetrexed sodium powder for solution for infusion and concentrate for solution for infusion's 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 HCPs;
- 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 reactions is collected continuously and regularly analyzed, including Periodic Safety Update Report (PSUR) assessment (if applicable) so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

13.2.1 Part VI – II.A: List of important risks and missing information

Important risks of pemetrexed sodium, powder for solution for infusion and concentrate for solution for infusion are risks that need special risk management activities to further investigate or minimize 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 sodium, powder for solution for infusion and 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).

Table 13-1 List of important risks and missing information

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

13.2.2 Part VI – II.B: Summary of important risks

The safety information in the proposed Product Information is aligned to Committee for Medicinal Products for Human Use (CHMP) and Pharmacovigilance Risk Assessment Committee (PRAC) rapporteurs preliminary joint assessment report (EMEA/H/C/004011/R/0008) dated 27 Mar 2020.

13.2.3 Part VI – II.C: Post-authorization development plan

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

There are no studies which are conditions of the marketing authorization or specific obligation of pemetrexed sodium, powder for solution for infusion and concentrate for solution for infusion.

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

There are no studies required for pemetrexed sodium, powder for solution for infusion and concentrate for solution for infusion.