PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for pemetrexed

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

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

I. The medicine and what it is used for

Pemetrexed is authorised for

Malignant pleural mesothelioma: Pemetrexed in combination with cisplatin is indicated for the treatment of chemotherapy naïve patients with unresectable malignant pleural mesothelioma.

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

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

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

It contains pemetrexed as the active substance and it is given by intravenous route of administration.

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

Important risks of pemetrexed, together with measures to minimise such 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 public (e.g. with or without prescription) can help to minimises its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse events 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 are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered by patients. 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. 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/use in special patient populations etc.);

Table 6 Part VI: Summary of safety concerns

List of important risks and missing information	
Important identified risks	None
Important potential risks	Medication errors (applicable only for Pemetrexed Mylan 25 mg/ml concentrate for solution for infusion, procedure number NL/H/3923)
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.

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

There are no studies required for pemetrexed.