Part VI: Summary of the Risk Management Plan

Summary of risk management plan for Pemetrexed Glenmark 100 mg powder for concentrate for solution for infusion and Pemetrexed Glenmark 500 mg powder for concentrate for solution for infusion (Pemetrexed)

This is a summary of the risk management plan (RMP) for Pemetrexed Glenmark 100 mg powder for concentrate for solution for infusion and Pemetrexed Glenmark 500 mg powder for concentrate for solution. The RMP details important risks of Pemetrexed Glenmark 100 mg powder for concentrate for solution for infusion and Pemetrexed Glenmark 500 mg powder for concentrate for solution, how these risks can be minimised, and how more information will be obtained about Pemetrexed Glenmark 100 mg powder for concentrate for solution for infusion and Pemetrexed Glenmark 500 mg powder for concentrate for solution risks and uncertainties (missing information).

Pemetrexed Glenmark 100 mg powder for concentrate for solution for infusion and Pemetrexed Glenmark 500 mg powder for concentrate for solution summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Pemetrexed Glenmark 100 mg powder for concentrate for solution for infusion and Pemetrexed Glenmark 500 mg powder for concentrate for solution should be used.

Important new concerns or changes to the current ones will be included in updates of Pemetrexed Glenmark 100 mg powder for concentrate for solution for infusion and Pemetrexed Glenmark 500 mg powder for concentrate for solution RMP.

I. The medicine and what it is used for

Pemetrexed Glenmark 100 mg powder for concentrate for solution for infusion and Pemetrexed Glenmark 500 mg powder for concentrate for solution is authorised for following indications:

Malignant pleural mesothelioma

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

Non-small cell lung cancer

Pemetrexed Glenmark 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 Glenmark 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 Glenmark 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 infusion.

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

Important risks of Pemetrexed Glenmark 100 mg powder for concentrate for solution for infusion and Pemetrexed Glenmark 500 mg powder for concentrate for solution, together with measures to minimise such risks and the proposed studies for learning more about Pemetrexed Glenmark 100 mg powder for

concentrate for solution for infusion and Pemetrexed Glenmark 500 mg powder for concentrate for solution 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 if PSUR is required by Health Authority, 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 Glenmark 100 mg powder for concentrate for solution for infusion and Pemetrexed Glenmark 500 mg powder for concentrate for solution are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely Pemetrexed Glenmark 100 mg powder for concentrate for solution for infusion and Pemetrexed Glenmark 500 mg powder for concentrate for solution.

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 Glenmark 100 mg powder for concentrate for solution for infusion and Pemetrexed Glenmark 500 mg powder for concentrate for solution. 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 risk(s)	• None
Important potential risk(s)	• None
Missing information	• None

II.B. Summary of important risk

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 Glenmark 100 mg powder for concentrate for solution for infusion and Pemetrexed Glenmark 500 mg powder for concentrate for solution

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

There are no studies required for Pemetrexed Glenmark 100 mg powder for concentrate for solution for infusion and Pemetrexed Glenmark 500 mg powder for concentrate for solution.