

Summary of Risk Management Plan for Pemetrexed Baxter 100 mg powder for concentrate for solution for infusion and Pemetrexed Baxter 500 mg powder for concentrate for solution for infusion (pemetrexed disodium)

This is a summary of the Risk Management Plan (RMP) for Pemetrexed Baxter 100 mg powder for concentrate for solution for infusion and Pemetrexed Baxter 500 mg powder for concentrate for solution for infusion (hereafter Pemetrexed Baxter). The RMP provides details on the risks of Pemetrexed Baxter, how these risks can be minimized, and how more information will be obtained about the risks. The Summary of Product Characteristics (SmPC) and Package Leaflet (PL) for Pemetrexed Baxter provide essential information to healthcare professionals and patients on how Pemetrexed Baxter should be used.

This summary of the RMP for Pemetrexed Baxter should be read in the context of all other related information, including the assessment report of the evaluation and its plain-language summary, all of which are part of the European Public Assessment Report (EPAR).

New safety concerns and/or changes to the current safety concerns will be included in future updates of the RMP.

I. The medicine and what it is used for

Pemetrexed Baxter is indicated for:

Malignant pleural mesothelioma

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

Non-small cell lung cancer

- Pemetrexed Baxter 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 Baxter 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 Baxter 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 disodium as the active substance, and it is given by intravenous infusion.

Further information about the evaluation of Pemetrexed Baxter's benefits can be found in the EPAR, including in its plain-language summary, available on the European Medicines Agency (EMA) website under the medicine's webpage:

<https://www.ema.europa.eu/en/medicines/human/EPAR/pemetrexed-baxter>

II. Risks associated with the medicine and activities to minimize or further characterize the risks

There are no risks included in the RMP for Pemetrexed Baxter; however, measures to minimize the risks for any medicinal products may be:

- Specific information, such as warnings, precautions, and advice on correct use, in the PL and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorized pack size – the amount of medicine in a pack is chosen so as 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).

Together, these measures constitute *routine risk minimization measures*.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including signal management activity and periodic safety update report assessment 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 medicinal products 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 medicinal products. Potential risks are concerns for which an association with the use of the medicinal product is possible based on available data, but this association has not been established yet and needs to be further monitored. Missing information refers to information on the safety of the medicinal product that is currently missing and further information may need to be collected (e.g., on the long-term use of the medicine).

There are no safety concerns for Pemetrexed Baxter.

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

II.B Summary of important risks and missing information

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

There are no safety concerns included in this RMP. All risks associated with the use of Pemetrexed are considered fully characterized and appropriately managed with routine risk minimization measures in the product information which are fully integrated into standard clinical practice.

II.C Post-authorization development plan

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

There are no studies which are conditions of the marketing authorization or specific obligations of Pemetrexed Baxter.

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

There are no studies required for Pemetrexed Baxter.