Part VI: Summary of the risk management plan

Summary of risk management plan for Pemetrexed SUN 100mg, 500mg and 1000 mg powder for concentrate for solution for infusion and Pemetrexed SUN 5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 10, 11mg/ml solution for infusion (Pemetrexed)

This is a summary of the risk management plan (RMP) for Pemetrexed SUN 100mg, 500mg and 1000 mg powder for concentrate for solution for infusion and Pemetrexed SUN 5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 10, 11 mg/ml solution for infusion.

The RMP details important risks of Pemetrexed 100mg, 500mg and 1000 mg powder for concentrate for solution for infusion and Pemetrexed SUN 5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 10, 11 mg/ml solution for infusion, how these risks can be minimised, and how more information will be obtained about Pemetrexed 100mg, 500mg, and 1000 mg powder for concentrate for solution for infusion and Pemetrexed SUN 5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 10, 11 mg/ml solution for infusion risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of Pemetrexed's RMP.

I. The medicine and what it is used for

Pemetrexed SUN 100mg, 500mg and 1000 mg powder for concentrate for solution for infusion and Pemetrexed SUN 5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 10, 11 mg/ml solution for infusion is indicated:

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 (see section 5.1).

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 (see section 5.1).

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 (see section 5.1).

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

Important risks of Pemetrexed SUN, together with measures to minimise such risks and the proposed studies for learning more about Pemetrexed'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, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of Pemetrexed is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Pemetrexed SUN 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 SUN. 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.

Summary of safety concerns	
Important identified risks	• **None**
Important potential risks	• **Medication error**
Missing information	• **None**

II.B Summary of important risks

The safety information in the proposed Product Information of Pemetrexed SUN is aligned to the reference medicinal product Alimta from Eli Lilly and Company Limited.

As the applied product has different dilution/handling instructions compared to the innovator, as the pharmaceutical form (solution for infusion) is different to the innovator (powder for concentrate for solution for infusion), medication errors was included as Important potential risks.

Important potential risk medication errors	
Evidence for linking the risk to the medicine	Medication error The MedDRA terms used for Pharmacovigilance is Medication error (preferred term [PT]). Potential mechanism: Potential risk of medication errors arise from different dilution instructions in the SmPC compared to the innovator Alimta. Evidence source(s) and strength of evidence: As the applied product has different dilution/handling instructions compared to the innovator, as the pharmaceutical form (solution for infusion) is different to the innovator (powder for concentrate for solution for infusion), medication errors was included as Important potential risks. Impact on the risk-benefit balance of the product: Since the risk can be adequately managed by appropriate risk minimization activities, the risk-benefit impact is acceptable.
Risk minimisation measures	<Routine risk minimisation measures> – **SPC sections 4.1, 4.2, 6.6** – **and Package Leaflet Section 3, 4 and 6** ***Pemetrexed SUN differs from reference product regarding the:*** – product name – concentration – pharmaceutical form (solution for infusion versus powder for concentrate for solution for infusion) – inbuilt distinguishing features in terms of appearance – **Prescription only medicine** <Additional risk minimisation measures> Not applicable.

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 SUN.

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

There are no studies required for Pemetrexed SUN.

Part VII: Annexes

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Annex 1 – EudraVigilance Interface

Not applicable.