Summary of Risk Management Plan for ARMISARTE 25 mg/ml concentrate for solution for infusion

This is a summary of the risk management plan (RMP) for ARMISARTE 25 mg/ml concentrate for solution for infusion (hereinafter referred to as Armisarte). The RMP details important risks of Armisarte, how these risks can be minimised, and how more information will be obtained about Armisarte's risks and uncertainties (missing information).

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

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

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

I. The Medicine and What It is used for

Armisarte is authorised for the treatment of malignant pleural mesothelioma in combination with cisplatin and in the treatment of non-small cell lung cancer in combination with cisplatin and as monotherapy in the maintenance treatment and second line treatment in patients with non-small cell lung cancer (see SmPC for the full indication). It contains pemetrexed as the active substance and it is given intravenously.

Further information about the evaluation of Armisarte’s benefits can be found in Armisarte’s EPAR, including in its plain-language summary, available on the EMA website, under the medicine’s webpage: https://www.ema.europa.eu/en/medicines/human/EPAR/armisarte-previously-pemetrexed-actavis.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Armisarte, together with measures to minimise such risks and the proposed studies for learning more about Armisarte'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*.

II.A List of Important Risks and Missing Information

Important risks of Armisarte 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 Armisarte. 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 1: Summary of Safety Concerns

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

II.B Summary of Important Risks

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

Table 2: Summary of Pharmacovigilance Activities and Risk Minimisation Activities by Safety Concern

Important potential risk: Medication errors	
Evidence for linking the risk to the medicine	PSUSA (Procedure No. EMEA/H/C/PSUSA/00002330/201802)
Risk factors and risk groups	Not known

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 Armisarte.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Armisarte.