Part VI: Summary of the risk management plan

Summary of risk management plan for Cabazitaxel Fresenius Kabi (Cabazitaxel)

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

Cabazitaxel Fresenius Kabi SmPC and its PL give essential information to healthcare professionals and patients on how Cabazitaxel Fresenius Kabi should be used.

Important new safety concerns or changes to the current ones will be included in updates of the Cabazitaxel Fresenius Kabi RMP.

I. The medicine and what it is used for

Cabazitaxel Fresenius Kabi in used in combination with prednisone or prednisolone for the treatment of adult patients with metastatic castration resistant prostate cancer previously treated with a docetaxel-containing regimen.

It contains cabazitaxel as active substance and it is administered via intravenous route only.

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

Important risks of Cabazitaxel Fresenius Kabi, together with measures to minimise such risks and the proposed studies for learning more about Cabazitaxel Fresenius Kabi 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 PL 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 Cabazitaxel Fresenius Kabi is not yet available, it is listed under "missing information" outlined in the next section.

II.A List of important risks and missing information

Important risks of Cabazitaxel Fresenius Kabi 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 Cabazitaxel Fresenius Kabi. 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 risks	– None
Important potential risks	– None
Missing information	– None

II.B Summary of important risks

The safety information in the proposed product information is aligned to the reference 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 Cabazitaxel Fresenius Kabi.

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

There are no on-going or closed studies for Cabazitaxel Fresenius Kabi**.**