Summary of risk management plan for Cabazitaxel Accord 60mg/3ml concentrate for solution for infusion (Cabazitaxel)

This is a summary of the risk management plan (RMP) for Cabazitaxel Accord 60 mg/3ml concentrate for solution for infusion. The RMP details important risks of Cabazitaxel Accord 60 mg/3ml concentrate for solution for infusion, how these risks can be minimised, and how more information will be obtained about Cabazitaxel Accord 60 mg/3ml concentrate for solution for infusion's risks and uncertainties (missing information).

Cabazitaxel Accord 60 mg/3ml concentrate for solution for infusion's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Cabazitaxel Accord 60 mg/3ml concentrate for solution for infusion should be used.

This summary of the RMP for Cabazitaxel Accord 60 mg/3ml concentrate for solution for infusion 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 Cabazitaxel Accord 60 mg/3ml concentrate for solution for infusion's RMP.

I. The medicine and what it is used for

Cabazitaxel Accord 60 mg/3ml concentrate for solution for infusion in combination with prednisone or prednisolone is indicated for the treatment of adult patients with metastatic castration resistant prostate cancer previously treated with a docetaxel containing regimen.

It contains cabazitaxel as the active substance and it is given as intravenous infusion.

Further information about the evaluation of Cabazitaxel Accord 60 mg/3ml concentrate for solution for infusion benefits can be found in Cabazitaxel's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage. Pre-authorisation RMP: Link to the EPAR summary landing page.

https://www.ema.europa.eu/en/medicines/human/EPAR/cabazitaxel-accord

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

Important risks of Cabazitaxel Accord 60 mg/3ml concentrate for solution for infusion together with measures to minimise such risks and the proposed studies for learning more about Cabazitaxel Accord 60 mg/3ml concentrate for solution for infusion'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 the case of Cabazitaxel Accord 60 mg/3ml concentrate for solution for infusion, these measures are supplemented with *additional risk minimisation measures* mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment (if applicable) and signal management activity, 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 Cabazitaxel Accord 60 mg/3ml concentrate for solution for infusion are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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 Accord 60 mg/3ml concentrate for solution for infusion. 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).

Important identified risks	• None
Important potential risks	• Medication error
Missing information	• None

II.B Summary of important risks

Important Potential Risks: Medication error	
Risk minimisation measures	Routine risk minimisation measures: • SmPC Sections 4.4, 6.3 and 6.6 • Specific statements regarding difference in concentration in vials of Cabazitaxel Accord compared to other cabazitaxel products and the need to appropriately dilute the product before use – in Sections 4.4, 6.3 and 6.6 of the SmPC. Additional risk minimisation measures: Communication Plan (DHPC letter) to ensure healthcare professionals and pharmacies using oncology agents are aware of the key messages regarding different concentration.
Additional pharmacovigilance activity:	Routine pharmacovigilance with specific query for cases where symptoms and signs of overdose have occurred to determine if medication error has occurred. Review of cases reported with "medication error" (Category 3 Study)

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 Accord 60 mg/3ml concentrate for solution for infusion.

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

Review of cases reported with "medication error" (Category 3 Study) to minimize the risk of "medication error".