Summary of risk management plan for Cabazitaxel 20 mg/ml concentrate for solution for infusion (cabazitaxel)

This is a summary of the risk management plan (RMP) for Cabazitaxel 20 mg/ml concentrate for solution for infusion. The RMP details important risks of Cabazitaxel 20 mg/ml concentrate for solution for infusion, how these risks can be minimised, and how more information will be obtained about risks and uncertainties of Cabazitaxel (important missing information).
The summary of product characteristics (SmPC) of Cabazitaxel 20 mg/ml concentrate for solution for infusion and its package leaflet give essential information to healthcare professionals and patients on how Cabazitaxel 20 mg/ml concentrate for solution for infusion should be used.

I. The medicine and what it is used for

Cabazitaxel 20 mg/ml concentrate for solution for infusion is proposed for the treatment of adult patients with metastatic castration resistant prostate cancer previously treated with a docetaxel-containing regimen (see SmPC for the full indication). It contains cabazitaxel as the active substance and it is given by intravenous infusion.

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

Important risks of Cabazitaxel 20 mg/ml concentrate for solution for infusion, together with measures to minimise such risks and the proposed studies for learning more about risks of cabazitaxel, 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 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 20 mg/ml is not yet available, it is listed under 'Important missing information' below.

II.A List of important risks and missing information

Important risks of cabazitaxel 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. 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);

Summary of safety concerns	
Important identified risks	– Neutropenia and associated clinical events (febrile neutropenia, neutropenic infection, neutropenic sepsis, sepsis, septic shock) – Gastro-intestinal disorders (vomiting and diarrhea) and associated complications (dehydration and electrolytes imbalance) – Renal failure – Peripheral neuropathy – Anaemia
Important potential risks	– Cardiac arrhythmia (ventricular arrhythmia and cardiac arrest) – Hepatic disorders (based on potential class-effect) – Lens toxicity (observed in a non-clinical study in rats) – Effect on male fertility (based on nonclinical studies) – Use in non-evaluated indications
Important missing information	– Drug-drug interaction (concomitant administration with CYP3A substrates or with inducers/ inhibitors of CYP3A) – Use in patients with hepatic impairment – Use in patients with moderate and renal impairment – Ethnicity other than Caucasian

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal 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 20 mg/ml concentrate for solution for infusion.

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

There are no studies required for Cabazitaxel 20 mg/ml.