12 Part VI: Summary of the risk management plan (RMP) for Cabazitaxel*, 10 mg/ml, Concentrate for solution for infusion

This is a summary of the RMP for cabazitaxel, 10 mg/ml, concentrate for solution for infusion. The RMP details important risks of cabazitaxel concentrate for solution for infusion, and how more information will be obtained about cabazitaxel concentrate for solution for infusion's risks and uncertainties (missing information).

Important new concerns or changes to the current ones will be included in updates of cabazitaxel, 10 mg/ml, concentrate for solution for infusion's RMP.

Cabazitaxel concentrate for solution for infusion's summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals (HCPs) and patients on how cabazitaxel should be used.

12.1 Part VI: I. The medicine and what it is used for

Cabazitaxel in combination with prednisone or prednisolone is authorized 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 administered via intravenous route as concentrate for solution for infusion (10 mg/ml).

12.2 Part VI: II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of cabazitaxel concentrate for solution for infusion, together with measures to minimize such risks and the proposed studies for learning more about cabazitaxel concentrate for solution for infusion's risks, are outlined below.

Measures to minimize 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 HCPs;
- Important advice on the medicine’s packaging;
- The authorized 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 minimize its risks.

Together, these measures constitute *routine risk minimization* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including Periodic Safety Update Report (PSUR) assessment (if applicable) 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 concentrate for solution for infusion is not yet available, it is listed under ‘missing information’ below.

in Austria
Cabazitaxel Sandoz 10 mg/ml - Konzentrat zur Herstellung einer Infusionslösung

12.2.1 Part VI – II.A: List of important risks and missing information

Important risks of cabazitaxel concentrate for solution for infusion are risks that need special risk management activities to further investigate or minimize 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 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).

Table 12-1 List of important risks and missing information

List of important risks and missing information	
Important identified risks	Neutropenia and associated clinical events
	Gastrointestinal disorders
	Renal failure
	Peripheral neuropathy
	Anemia
	Respiratory disorders
	Use in severe hepatic impairment
Important potential risks	Cardiac arrhythmia
	Hepatic disorders
	Lens toxicity
	Effect on male fertility
	Use in non-evaluated indications
	Drug-drug interaction (concomitant administration with inducers or inhibitors of CYP3A)
	Mild and moderate hepatic impairment
	Teratogenicity
	Drug preparation errors
Missing information	Ethnicity other than Caucasian

12.2.2 Part VI – II.B: Summary of important risks

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

12.2.3 Part VI – II.C: Post-authorization development plan

12.2.3.1 II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of cabazitaxel concentrate for solution for infusion.

12.2.3.2 II.C.2. Other studies in post-authorization development plan

There are no studies required for cabazitaxel concentrate for solution for infusion.