Part VI: Summary of the risk management plan

Summary of risk management plan for <Product name> 20 mg/ml concentrate for solution for infusion (Cabazitaxel)

This is a summary of the risk management plan (RMP) for <Product name>. The RMP details important risks of <Product name>, how these risks can be minimised, and how more information will be obtained about <Product name>'s risks and uncertainties (missing information).

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

I. The medicine and what it is used for

<Product name> is authorised 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 (see SmPC for the full indication). It contains cabazitaxel as the active substance and it is given intravenously.

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

Important risks of <Product name>, together with measures to minimise such risks and the proposed studies for learning more about <Product name>'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.

If important information that may affect the safe use of <Product name> is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of <Product name> 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 <Product name>. 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, hemorrhage and perforation; colitis, enterocolitis, gastritis, neutropenic colitis; and ileus and intestinal obstruction) and associated complications (dehydration and electrolyte imbalance) • Renal failure • Peripheral neuropathy • Anaemia • Drug preparation errors • Respiratory disorders (acute respiratory distress syndrome, interstitial pneumonia / pneumonitis, interstitial lung disease and pulmonary fibrosis • Use in severe hepatic impairment
Important potential risks	• Cardiac arrhythmia (ventricular arrhythmia and cardiac arrest) • Hepatic disorders • Lens toxicity • Effects on male fertility • Drug-drug interaction (concomitant administration with inducers or with inhibitors of CYP3A) • Mild and moderate hepatic impairment • Teratogenicity • Use in non-evaluated indications
Missing information	• 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 <Product name>.

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

There are no studies required for <Product name>.