

Part VI: Summary of the Risk Management Plan

Summary of Risk Management Plan for Cabazitaxel 10 mg/ml concentrate for solution for infusion*

*In RMS-AT:

- **Cabazitaxel ratiopharm 10mg/ml Konzentrat zur Herstellung einer Infusionslösung
for procedure AT/H/1027/001/DC**
- **Cabazitaxel TEVA 10mg/ml Konzentrat zur Herstellung einer Infusionslösung
for procedure AT/H/1209/001/DC**

This is a summary of the risk management plan (RMP) for Cabazitaxel 10 mg/ml concentrate for solution for infusion. The RMP details important risks of Cabazitaxel 10 mg/ml concentrate for solution for infusion, how these risks can be minimised, and how more information will be obtained about Cabazitaxel 10 mg/ml concentrate for solution for infusion risks and uncertainties (missing information).

Cabazitaxel 10 mg/ml concentrate for solution for infusion summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Cabazitaxel 10 mg/ml concentrate for solution for infusion should be used.

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

I. The Medicine and What It is used for

Cabazitaxel 10 mg/ml concentrate for solution for infusion is authorised in combination with prednisone or prednisolone 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 administered intravenously after dilution.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Cabazitaxel 10 mg/ml concentrate for solution for infusion, together with measures to minimise such risks and the proposed studies for learning more about Cabazitaxel 10 mg/ml concentrate for solution for infusion risks, if any, 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, including PSUR assessment 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 10 mg/ml 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 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 10 mg/ml 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 5: Summary of Safety Concerns

List of important risks and missing information	
Important identified risks	<ul style="list-style-type: none"> • None
Important potential risks	<ul style="list-style-type: none"> • None
Missing information	<ul style="list-style-type: none"> • None

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.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Cabazitaxel.