

## **Summary of risk management plan for JEVTANA (Cabazitaxel)**

This is a summary of the RMP for JEVTANA. The RMP details important risks of JEVTANA how these risks can be minimized, and how more information will be obtained about JEVTANA's risks and uncertainties (missing information).

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

This summary of the RMP for JEVTANA 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 JEVTANA's RMP.

### **1. THE MEDICINE AND WHAT IT IS USED FOR**

JEVTANA in combination with prednisone or prednisolone is indicated for the treatment of patients with castration resistant metastatic prostate cancer previously treated with a docetaxel containing regimen (see SmPC for the full indication). It contains JEVTANA as the active substance and it is given by intravenous infusion.

Further information about the evaluation of JEVTANA's benefits can be found in JEVTANA's EPAR, including in its plain-language summary, available on the European Medicines Agency (EMA) website, under the medicine's webpage:

Refer to EPAR ref. EMA/H/C/002018 dated 09 October 2019 available on the EMA website at the following link:

<https://www.ema.europa.eu/en/medicines/human/EPAR/jevtana>

### **2. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMIZE OR FURTHER CHARACTERIZE THE RISKS**

Important risks of JEVTANA, together with measures to minimize such risks and the proposed studies for learning more about JEVTANA's risks, are outlined in the next sections.

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 healthcare professionals;
- 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 (eg, with or without prescription) can help to minimize its risks.

Together, these measures constitute routine risk minimization measures.

If important information that may affect the safe use of JEVTANA is not yet available, it is listed under “missing information” outlined in the next section.

## **2.1 List of important risks and missing information**

Important risks of JEVTANA 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 JEVTANA. 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 (eg, on the long-term use of the medicine).

**Table 1 - List of important risks and missing information**

<b>Important identified risks</b>	None
<b>Important potential risks</b>	None
<b>Missing information</b>	None

## **2.2 Summary of important risks**

Not applicable.

## **2.3 Post-authorization development plan**

### ***2.3.1 Studies which are conditions of the marketing authorization***

There are no studies which are conditions of the marketing authorization or specific obligation of JEVTANA.

### ***2.3.2 Other studies in post-authorization development plan***

There are no studies required for JEVTANA.