

## **Summary of risk management plan for TAXOTERE (Docetaxel)**

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

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

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

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

TAXOTERE is authorized for breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma and head and neck cancer (see SmPC for the full indication).

It contains TAXOTERE as the active substance and it is given by infusion.

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

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

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

Important risks of TAXOTERE, together with measures to minimize such risks and the proposed studies for learning more about TAXOTERE'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 package leaflet 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 (eg, with or without prescription) can help to minimize its risks.

Together, these measures constitute routine risk minimization measures.

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

Important risks of TAXOTERE 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 TAXOTERE. 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 risk</b> | None |
| <b>Important potential risk</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 TAXOTERE.

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

There are no studies required for TAXOTERE.