

Part VI: Summary of the risk management plan

Summary of risk management plan for Paclitaxel 6 mg/ml concentrate for solution for infusion and Paclitaxel 5 mg/ml powder for dispersion for infusion (hereinafter referred to as paclitaxel).

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

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

Important new concerns or changes to the current ones will be included in updates of paclitaxel's RMP.

I. The medicine and what it is used for

Paclitaxel, 5 mg/ml powder for dispersion for infusion is authorized for:

The treatment of metastatic breast cancer as monotherapy in adult patients who have failed first-line treatment for metastatic disease and for whom standard, anthracycline containing therapy is not indicated.

Paclitaxel in combination with gemcitabine is indicated for the first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas.

Paclitaxel in combination with carboplatin is indicated for the first-line treatment of non-small cell lung cancer in adult patients who are not candidates for potentially curative surgery and/or radiation therapy.

Paclitaxel, 6 mg/ml concentrate for solution for infusion is authorized for:

Ovarian carcinoma: In the first-line chemotherapy of ovarian cancer, paclitaxel is indicated for the treatment of patients with advanced carcinoma of the ovary or with residual disease (> 1 cm) after initial laparotomy, in combination with cisplatin.

In the second-line chemotherapy of ovarian cancer, paclitaxel is indicated for the treatment of metastatic carcinoma of the ovary after failure of standard, platinum containing therapy.

Breast carcinoma: In the adjuvant setting, paclitaxel is indicated for the treatment of patients with node-positive breast carcinoma following anthracycline and cyclophosphamide (AC) therapy. Adjuvant treatment with paclitaxel should be regarded as an alternative to extended AC therapy.

Paclitaxel is indicated for the initial treatment of locally advanced or metastatic breast cancer either in combination with an anthracycline in patients for whom anthracycline therapy is suitable, or in combination with trastuzumab, in patients who over-express HER-2 at a

3+ level as determined by immunohistochemistry and for whom an anthracycline is not suitable.

As a single agent, paclitaxel is indicated for the treatment of metastatic carcinoma of the breast in patients who have failed, or are not candidates for standard, anthracycline containing therapy.

Advanced non-small cell lung carcinoma: Paclitaxel, in combination with cisplatin, is indicated for the treatment of non-small cell lung carcinoma (NSCLC) in patients who are not candidates for potentially curative surgery and/or radiation therapy.

AIDS-related Kaposi's sarcoma: Paclitaxel is indicated for the treatment of patients with advanced AIDS-related Kaposi's sarcoma (KS) who have failed prior liposomal anthracycline therapy.

It contains paclitaxel as an active substance and is taken intravenously as concentrate for solution for infusion (6 mg/ml) or powder for dispersion for infusion (5 mg/ml).

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

Important risks of paclitaxel, together with measures to minimize such risks and the proposed studies for learning more about paclitaxel'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 package leaflet 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 (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 analysed 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 paclitaxel 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 paclitaxel. 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).

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	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 authorization or specific obligation of paclitaxel.

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

There are no studies required for paclitaxel.