Part VI: Summary of the risk management plan

Summary of risk management plan for Paclitaxel Albumin 5 mg/ml powder for dispersion for infusion (Paclitaxel Albumin)

This is a summary of the risk management plan (RMP) for Paclitaxel Albumin 5mg/ml powder for dispersion for infusion . The RMP details important risks of Paclitaxel Albumin, how these risks can be minimised, and how more information will be obtained about Paclitaxel Albumin's risks and uncertainties (missing information).

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

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

I. The medicine and what it is used for

Paclitaxel Albumin is authorised for:

Paclitaxel Albumin monotherapy is indicated for the treatment of metastatic breast cancer in adult patients who have failed first-line treatment for metastatic disease and for whom standard, anthracycline containing therapy is not indicated (see section 4.4).

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

Paclitaxel Albumin 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.See SmPC for the full indication. It contains Pacliatxel Albumin as the active substance and it is given by intravenous administration.

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

Important risks of Paclitaxel Albumin, together with measures to minimise such risks and the proposed studies for learning more about Paclitaxel Albumin'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.

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 safety concerns and missing information

Important risks of Paclitaxel Albumin are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered/taken. 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 Albumin. 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).

There are no important identified or potential risks or missing information.

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 authorisation or specific obligation of Paclitaxel Albumin.

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

There are no studies in post-authorisation development plan required for Paclitaxel Albumin.