Part VI: Summary of the risk management plan

Summary of risk management plan for Gemcitabine 100 mg/ml Concentrate for Solution for Infusion (Gemcitabine)

This is a summary of the risk management plan (RMP) for Gemcitabine 100 mg/ml Concentrate for Solution for Infusion. The RMP details important risks of Gemcitabine 100 mg/ml Concentrate for Solution for Infusion , how these risks can be minimised, and how more information will be obtained about Gemcitabine 100 mg/ml Concentrate for Solution for Infusion's risks and uncertainties (missing information).

Gemcitabine 100 mg/ml Concentrate for Solution for Infusion's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Gemcitabine 100 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 Gemcitabine 100 mg/ml Concentrate for Solution for Infusion's RMP.

I. The medicine and what it is used for

Gemcitabine is indicated for the treatment of locally advanced or metastatic bladder cancer in combination with cisplatin.

Gemcitabine is indicated for treatment of patients with locally advanced or metastatic adenocarcinoma of the pancreas.

Gemcitabine, in combination with cisplatin, is indicated as first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC). Gemcitabine monotherapy can be considered in elderly patients or those with performance status 2.

Gemcitabine is indicated for the treatment of patients with locally advanced or metastatic epithelial ovarian carcinoma, in combination with carboplatin, in patients with relapsed disease following a recurrence-free interval of at least 6 months after platinum-based, first-line therapy.

Gemcitabine, in combination with paclitaxel, is indicated for the treatment of patients with unresectable, locally recurrent or metastatic breast cancer who have relapsed following adjuvant/neoadjuvant chemotherapy. Prior chemotherapy should have included an anthracycline unless clinically contraindicated.

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It contains gemcitabine (as gemcitabine hydrochloride) and given by intravenous infusion.

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

Important risks of Gemcitabine 100 mg/ml Concentrate for Solution for Infusion together with measures to minimise such risks and the proposed studies for learning more about Gemcitabine 100 mg/ml Concentrate for Solution for Infusion'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 during signal management activity, 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 Gemcitabine 100 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 Gemcitabine 100 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

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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).

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 Gemcitabine 100 mg/ml Concentrate for Solution for Infusion.

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

There are no studies required for Gemcitabine 100 mg/ml Concentrate for Solution for Infusion.

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