Summary of risk management plan for Zolsketil pegylated liposomal 2 mg/ml concentrate for dispersion for infusion (doxorubicin hydrochloride)

This is a summary of the risk management plan (RMP) for Zolsketil pegylated liposomal 2 mg/ml concentrate for dispersion for infusion. The RMP details important risks of Zolsketil pegylated liposomal 2 mg/ml concentrate for dispersion for infusion, how these risks can be minimised, and how more information will be obtained about Zolsketil pegylated liposomal 2 mg/ml concentrate for dispersion for infusion's risks and uncertainties (missing information).

Zolsketil pegylated liposomal 2 mg/ml concentrate for dispersion for infusion's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Zolsketil pegylated liposomal 2 mg/ml concentrate for dispersion for infusion should be used.

This summary of the RMP for Zolsketil pegylated liposomal 2 mg/ml concentrate for dispersion for infusion 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 Zolsketil pegylated liposomal 2 mg/ml concentrate for dispersion for infusion's RMP.

I. The medicine and what it is used for

Zolsketil pegylated liposomal 2 mg/ml concentrate for dispersion for infusion is indicated:

- As monotherapy for patients with metastatic breast cancer, where there is an increased cardiac risk.
- For treatment of advanced ovarian cancer in women who have failed a first-line platinum-based chemotherapy regimen.
- In combination with bortezomib for the treatment of progressive multiple myeloma in patients who have received at least one prior therapy and who have already undergone or are unsuitable for bone marrow transplant.
- For treatment of AIDS-related Kaposi's sarcoma (KS) in patients with low CD4 counts (< 200 CD4 lymphocytes/mm^3) and extensive mucocutaneous or visceral disease.

Zolsketil pegylated liposomal 2 mg/ml concentrate for dispersion for infusion is indicated may be used as first-line systemic chemotherapy, or as second line chemotherapy in AIDS-KS patients with disease that has progressed with, or in patients intolerant to, prior combination systemic chemotherapy comprising at least two of the following agents: a vinca alkaloid, bleomycin and standard doxorubicin (or other anthracycline).

It contains doxorubicin hydrochloride as the active substance and it is given by intravenous route.

Further information about the evaluation of Zolsketil pegylated liposomal 2 mg/ml concentrate for dispersion for infusion's benefits can be found in Zolsketil pegylated liposomal 2 mg/ml concentrate for dispersion for infusion'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/zolsketil-pegylated-liposomal

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

Important risks of Zolsketil pegylated liposomal 2 mg/ml concentrate for dispersion for infusion together with measures to minimise such risks and the proposed studies for learning more about Zolsketil pegylated liposomal 2 mg/ml concentrate for dispersion 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, including PSUR assessment and 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 Zolsketil pegylated liposomal 2 mg/ml concentrate for dispersion 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 Zolsketil pegylated liposomal 2 mg/ml concentrate for dispersion 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 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 Zolsketil pegylated liposomal 2 mg/ml concentrate for dispersion for infusion.

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

There are no studies required for Zolsketil pegylated liposomal 2 mg/ml concentrate for dispersion for infusion.