Summary of risk management plan for Plerixafor Seacross 20 mg/ml solution for injection (Plerixafor)

This is a summary of the risk management plan (RMP) for Plerixafor Seacross 20 mg/ml solution for injection. The RMP details important risks of Plerixafor Seacross 20 mg/ml solution for injection, and how more information will be obtained about Plerixafor Seacross 20 mg/ml solution for injection's risks and uncertainties (missing information).

Plerixafor Seacross 20 mg/ml solution for injection's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Plerixafor Seacross 20 mg/ml solution for injection should be used.

Important new concerns or changes to the current ones will be included in updates of Plerixafor Seacross 20 mg/ml solution for injection's RMP.

I. The medicine and what it is used for

Plerixafor Seacross 20 mg/ml solution for injection is authorised for:

Adult patients

Plerixafor is indicated in combination with granulocyte-colony stimulating factor (G-CSF) to enhance mobilisation of haematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in adult patients with lymphoma or multiple myeloma whose cells mobilise poorly (see section 4.2 of SmPC).

Paediatric patients (1 to less than 18 years)

Plerixafor is indicated in combination with G-CSF to enhance mobilisation of haematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in children with lymphoma or solid malignant tumours, either:

- pre-emptively, when circulating stem cell count on the predicted day of collection after adequate mobilization with G-CSF (with or without chemotherapy) is expected to be insufficient with regards to desired hematopoietic stem cells yield, or
- Who previously failed to collect sufficient haematopoietic stem cells (see section 4.2).

(See SmPC for the full indication). It contains Plerixafor as the active substance and it is given by subcutaneous injection.

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

Important risks of Plerixafor Seacross 20 mg/ml solution for injection, together with measures to minimise such risks and the proposed studies for learning more about Plerixafor Seacross 20 mg/ml solution for injection'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.

If important information that may affect the safe use of Plerixafor Seacross 20 mg/ml solution for injection is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Plerixafor Seacross 20 mg/ml solution for injection 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 Plerixafor Seacross 20 mg/ml solution for injection. 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	Splenomegaly and splenic rupture
Important potential risks	• Interstitial lung disease; • Myocardial Infarction; • Tumor cell mobilization; • Drug level NOS increased; • Anxiety, hallucination (including hallucination, visual hallucination, and auditory hallucination); • Effect on embryo-fetal development (including teratogenicity and fetal growth restriction).
Missing information	Safety profile in paediatric under 2 years of age.

NOS: Not Otherwise Specified.

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 Plerixafor Seacross 20 mg/ml solution for injection.

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

There are no studies required for Plerixafor Seacross 20 mg/ml solution for injection.