

Part VI: Summary of the Risk Management Plan

Summary of Risk Management Plan for PLERIXAFOR 20 mg/ml solution for injection

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

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

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

I. The Medicine and What It is used for

Plerixafor is authorised 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 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, together with measures to minimise such risks and the proposed studies for learning more about Plerixafor'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 is not yet available, it is listed under 'missing information' below.

II.A List of Important Risks and Missing Information

Important risks of Plerixafor 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. 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).

Table 4: Summary of Safety Concerns

List of important risks and missing information	
Important identified risks	<input type="checkbox"/> Splenomegaly and splenic rupture
Important potential risks	<ul style="list-style-type: none"> • Interstitial lung disease • Myocardial infarction • Tumour cell mobilization • Drug level NOS¹ increased • Anxiety, hallucination (including hallucination, visual hallucination, and auditory hallucination) • Effect on embryo-foetal development (including teratogenicity and foetal growth restriction)
Missing information	<input type="checkbox"/> Safety profile in paediatric under 2 years of age

¹ 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.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Plerixafor.