13 October 2022
EMA/CHMP/830349/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Plerixafor Accord

plerixafor

On 13 October 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Plerixafor Accord, intended for the enhanced mobilisation of progenitor cells prior to stem cell transplantation in patients with lymphoma and multiple myeloma whose haematopoietic stem cells mobilise poorly. The applicant for this medicinal product is Accord Healthcare S.L.U.

Plerixafor Accord will be available as a 20 mg/ml solution for injection. The active substance of Plerixafor Accord is plerixafor, an immunostimulant (ATC code: L03AX16). Plerixafor is a bicyclam derivative, a selective reversible antagonist of the CXCR4 chemokine receptor, and blocks binding of its cognate ligand, stromal cell-derived factor-1α (SDF-1α, also known as CXCL12). Plerixafor increases the mobilization of haematopoietic stem cells (HSCs) to the peripheral blood where they can be collected for HSC transplantation.

Plerixafor Accord is a generic of Mozobil, which has been authorised in the EU since 31 July 2009. Studies have demonstrated the satisfactory quality of Plerixafor Accord. Since both the reference and the generic medicine are aqueous solutions for subcutaneous injection, and contain the same active substance in the same concentration and identical amounts of the same excipients, no bioequivalence studies are required. A question and answer document on generic medicines can be found here.

The full indication is:

Adult patients

Plerixafor Accord 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.

Paediatric patients (1 to less than 18 years)

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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Plerixafor Accord 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.

Plerixafor Accord should be prescribed by physicians experienced in oncology and/or haematology. The mobilisation and apheresis procedures should be performed in collaboration with an oncology-haematology centre with acceptable experience in this field and where the monitoring of haematopoietic progenitor cells can be correctly performed.

Plerixafor Accord should be administered by subcutaneous injection.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.