

**MOZOBIL
(plerixafor)****RATIONALE FOR INCLUSION IN PA PROGRAM****Background**

Mozobil (plerixafor) inhibits the CXCR4 chemokine receptor and blocks binding of its cognate ligand, stromal cell-derived factor-1 α (SDF-1 α). SDF-1 α and CXCR4 play a role in the trafficking and homing of human hematopoietic stem cells (HSCs) to the marrow compartment. Once in the marrow, stem cell CXCR4 can act to help anchor these cells to the marrow matrix, either directly via SDF-1 α or through the induction of other adhesion molecules. Treatment with Mozobil results in leukocytosis and elevations in circulating hematopoietic progenitor cells (1).

Regulatory Status

FDA approved indication: Mozobil is indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells (HSCs) to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma and multiple myeloma (1).

Serious hypersensitivity reactions, including anaphylactic-type reactions, have occurred in patients receiving Mozobil. Patients should be observed for signs and symptoms of hypersensitivity during and after Mozobil administration for at least 30 minutes and until clinically stable following completion of each administration (1).

Mozobil may cause mobilization of leukemic cells and subsequent contamination of the apheresis product. Therefore, Mozobil is not intended for HSC mobilization and harvest in patients with leukemia (1).

Leukocytosis and thrombocytopenia have been observed in patients receiving Mozobil. Platelet counts and white blood cell counts should be monitored in all patients who receive Mozobil (1).

Mozobil can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use an effective form of contraception during treatment with Mozobil and for one week after the final dose (1).

The safety and effectiveness of Mozobil in pediatric patients less than 18 years of age have not been established (1).



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Summary

Mozobil (plerixafor) inhibits the CXCR4 chemokine receptor and blocks binding of its cognate ligand, stromal cell-derived factor-1 α (SDF-1 α). SDF-1 α and CXCR4 play a role in the trafficking and homing of human hematopoietic stem cells (HSCs) to the marrow compartment. Once in the marrow, stem cell CXCR4 can act to help anchor these cells to the marrow matrix, either directly via SDF-1 α or through the induction of other adhesion molecules. Treatment with Mozobil results in leukocytosis and elevations in circulating hematopoietic progenitor cells. The safety and effectiveness of Mozobil in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate and cost-effective use of Mozobil while maintaining optimal therapeutic outcomes.

References

1. Mozobil [package insert]. Cambridge, MA: Genzyme Corporation; August 2020.