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| **Plerixafor Injection, 24 mg/1.2 mL (20 mg/mL), Single dose Vial** |
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| **S.No.** | **Category** | **Question** | **Answer** |
| **Clinical Particulars** |
| 1 | Use/Indication | What is the product indicated for? | Plerixafor injection, a hematopoietic stem cell mobilizer, is indicated in combination with granulocyte colony stimulating factor (G-CSF) to mobilize hematopoietic stem cell (HSCs) to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin’s lymphoma or multiple myeloma. |
| 2 | Dosage | What is the recommended dosage? | The recommended dose of plerixafor injection by subcutaneous injection is based on body weight:* 20 mg fixed dose or 0.24 mg/kg of body weight for patients weighing less than or equal to 83 kg.
* 0.24 mg/kg of body weight for patients weighing greater than 83 kg

 ***(For complete, please refer prescribing information****)* |
| 3 | Administration | Use in Pediatric Population | The safety and effectiveness of plerixafor have not been established in pediatric patients. |
| 4 | Administration | Use in Geriatric Population | No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. This drug is known to be mainly excreted by the kidney, no dose modifications are necessary in elderly individuals with normal renal function. In general, care should be taken in dose selection for elderly patients due to the greater frequency of decreased renal function with advanced age. Dosage adjustment in elderly patients with CL less than or equal to 50 mL/min is recommended. |
| 5 | Mechanism  | Mechanism of Action | Plerixafor is an inhibitor of the CXCR4 chemokine receptor and blocks binding of its cognate ligand, stromal cell-derived factor-1α (SDF-1α). SDF-1α and CXCR4 are recognized to 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-1α or through the induction of other adhesion molecules.  |
| 7 | Warning |  Warnings and precautions | * Anaphylactic Shock and Serious Hypersensitivity Reactions have occurred. Monitor patients during and after completion of plerixafor administration.
* Tumor Cell Mobilization in Leukemia Patients: Plerixafor may mobilize leukemic cells and should not be used in leukemia patients.
* Hematologic Effects: Increased circulating leukocytes and decreased platelet counts have been observed. Monitor blood cell counts and platelet counts during plerixafor use.
* Potential for Tumor Cell Mobilization: Tumor cells may be released from marrow during HSC mobilization with plerixafor and G-CSF. Effect of reinfusion of tumor cells is unknown.
* Splenic Rupture: Evaluate patients who report left upper abdominal and/or scapular or shoulder pain.
* Embryo-Fetal Toxicity: Can cause fetal harm. Advise women not to become pregnant when taking plerixafor
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| 8 | Lactation | Use in Lactation | There are no data on the presence of plerixafor in human milk, the effect on the breastfed child, or the effect on milk production. Because of the potential serious adverse reactions in the breastfed child, advise females that breastfeeding is not recommended during treatment with plerixafor and for one week after the final dose. |
| 9 | Pregnancy | Use in Pregnancy | Advise pregnant women of the potential risk to the fetus.Advise women of reproductive potential to avoid becoming pregnant while receiving treatment with plerixafor. |
| 10 | Storage | What are the storage conditions? | Store at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F).  |
| 11 | Dispensing | How to Dispense? | As prescribed by physician. |
| 12 | Contraindication | What are the contraindications of (medication)? | Plerixafor is contraindicated in patients with a history of hypersensitivity to Plerixafor. |
| **Miscellaneous** |
| 15 | Miscellaneous | May I know the product availability? | Novadoz Pharmaceuticals products are only available through pharmacies, wholesalers, and other authorized distributors. See our ADR (authorized distributors of record) page at NovadozPharma.com to learn more about where to find our products. |
| 16 | Miscellaneous | May I know about return, refunds and reimbursement? | Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500 |
| 17 | Miscellaneous | Do you have any patient's assistance program? | Novadoz Pharmaceuticals does not offer patient assistance programs at this time. The company that produces the brand version of your product may or may not offer such a program. Please check for access & eligibility requirements with that company |
| 18 | Miscellaneous | Why does my pharmacy, that used to fill your generic formulation of a particular medicine, no longer fills my prescription with Novadoz formulation? | Please check with your pharmacy as to why your prescription is not a Novadoz Pharmaceuticals product. You may refer to NovadozPharma.com ADR (authorized distributor of record) page to learn where to find our products |
| 19 | Miscellaneous | May I know where is this product manufactured? | **Manufactured by**:MSN Laboratories Private LimitedTelangana – 509 228, INDIA**Distributed by**:Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714  |