



Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021

Introduction Type: New Item

Final Version

Date: 24.06.2023

| PRODUCT INFORMATION | | | | SPECIAL HANDLING AND STORAGE REQUIREMENTS* | | | |
|--|------------------------------|---|----------------|---|-----------------------------|--|--|
| Company Name: Eugia US LLC | | Application: ANDA | | a. Temperature – Indicate the USP temperature range for this product. | | | |
| Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): | | | | Temperature Range: <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/> | | | |
| Medical Device Class, if applicable: | | | | Other Temperature Range Requirement (write in): <input type="text"/> | | | |
| DUNS: | | | | Notes: <input type="text"/> | | | |
| Proprietary Name (If Applicable) and Established Name: Plerixafor Injection | | Unit of Use NDC: 55150-356-01 | | UPC: 355150356010 | | Is this product to be shipped to customers on ice? <input type="checkbox"/> No | |
| Selling Unit NDC: 55150-356-01 | | CVX Code: | | MVX Code: | | Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No | |
| UDI: | | Description: Plerixafor Injection 24 mg per 1.2 mL (20 mg/mL) One single-dose vial | | b. Contact for temperature excursion questions: | | | |
| Active Ingredient(s): Plerixafor Injection | | URL for Additional Product Information: | | Name: <input type="text"/> | | | |
| Address: 279 Princeton-Hightstown Road | | Address 2: | | Number: <input type="text"/> | | | |
| City: East Windsor | | State: NJ | | Group E-mail: <input type="text"/> | | | |
| Key Contact: | | Email: | | c. Special regulations for product in any states? <input type="checkbox"/> No | | | |
| Phone Number: 888-238-7880 | | Fax: 732-355-9449 | | Special returns requirements for this product? <input type="checkbox"/> No | | | |
| Product Therapeutic Classification: | | | | d. Store product (unit of sale) upright? <input type="checkbox"/> | | | |
| | | | | Protect product (unit of sale) from light? <input type="checkbox"/> | | | |
| | | | | e. Shelf life: <input type="text"/> Months | | | |
| | | | | Initial shelf life at launch (if different): <input type="text"/> Months | | | |
| ADDITIONAL PRODUCT INFORMATION | | | | PRODUCT DESCRIPTION INFORMATION | | | |
| The product is? a legend device? <input type="checkbox"/> | | Is the Product... <input type="checkbox"/> | | Size: 1 Vial | | | |
| if yes, enter class # <input type="text"/> | | Is the Product... <input type="checkbox"/> | | Strength: 24 mg per 1.2 mL (20 mg/mL) | | | |
| if yes, list NDCs of component parts reverse numbered? <input type="text"/> | | Orphan Drug Status <input type="checkbox"/> | | Dosage Form: Injection (Liquid) | | | |
| if yes, list NDCs of component parts co-licensed? <input type="text"/> | | FDA Approval Status <input type="text"/> | | Product Shape: Vial Pack | | | |
| latex-free? <input type="checkbox"/> | | Allergens Present <input type="text"/> | | Product Color: <input type="text"/> | | | |
| preservative-free? <input type="checkbox"/> | | Country of Origin: India | | Product Imprint: <input type="text"/> | | | |
| correctional institution block? <input type="checkbox"/> | | Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No | | | | | |
| opioid? <input type="checkbox"/> | | | | | | | |
| Cannabinoid? <input type="checkbox"/> | | | | | | | |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/> | | | | | | | |
| If Unit Dose, indicate NDC here: <input type="text"/> | | | | | | | |
| ORDER INFORMATION | | | | | | | |
| Unit of Sale | | | | What is the NDC selling unit? | | | |
| <input checked="" type="checkbox"/> Bottle | | | | 1 Box of 1 Vial (55150-356-01) | | | |
| <input type="checkbox"/> Box/Carton | | | | (Write-in, e.g. 1 Box of 10 Vials) | | | |
| <input type="checkbox"/> Ampule | | | | Minimum order quantity? <input type="text"/> | | | |
| <input type="checkbox"/> Glass | | | | If Yes, how many of which package type? | | | |
| <input type="checkbox"/> Tube | | | | <input type="text"/> Each | | | |
| <input type="checkbox"/> Vial Liquid Sgl | | | | <input type="text"/> Inner/ Carton/ Pack | | | |
| <input type="checkbox"/> Vial Liquid Multi | | | | <input type="text"/> Case | | | |
| <input type="checkbox"/> Vial Powder Sgl | | | | | | | |
| <input type="checkbox"/> Vial Powder Multi | | | | | | | |
| <input type="checkbox"/> Other: Write In | | | | | | | |
| PHARMACY ORDER / BILL UNIT | | | | | | | |
| Rec. sell unit to customer? <input type="text" value="1 Vial"/> | | | | Rx billing unit to pharmacy: | | | |
| (Write-in, e.g. 1 Vial) | | | | <input checked="" type="checkbox"/> Each | | | |
| | | | | <input type="checkbox"/> Gram | | | |
| | | | | <input checked="" type="checkbox"/> Milliliter | | | |
| ITEM AND PACKING INFORMATION | | | | | | | |
| | Weight Lbs. | Dimensions (US msmts.) | | | Volume (Cube) | Saleable # Pieces | |
| | | Depth | Width | Height | | | |
| Item/Each: | 0.06 | 1.81 | 1.65 | 3.35 | 10.004775 | 1 | |
| Box/Carton/Bundle/Inner Pack: | 0.949 | 11.65 | 3.78 | 4.33 | 190.68021 | 12 | |
| Case: | 4.897 | 12.598 | 8.465 | 9.843 | 1049.6779 | 48 | |
| Pallet: | Sea: 346.456 Air: 424.814 | 48 | 40 | Sea: 46.34 Air: 54.61 | Sea: 80372.8 Air: 104851 | Sea: 3072 Air: 3840 | |
| GTIN AND HIBCC PRODUCT INFORMATION | | | | COST INFORMATION | | | |
| Saleable Unit of Measure | Saleable Quantity | HIBCC | GTIN-14 | Unit of Use GTIN-14 | | | |
| <input checked="" type="checkbox"/> Item/Each | 1 | | 00355150356010 | | | | |
| <input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack | 12 | | 30355150356011 | | | | |
| <input checked="" type="checkbox"/> Case | 48 | | 50355150356015 | | | | |
| <input checked="" type="checkbox"/> Pallet | 3840 | | 70355150356019 | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| WHOLESALE USE ONLY: | | | | Regular Cost <input type="text"/> | | | |
| Invoice Cost (WAC) (\$) <input type="text"/> | | | | Vendor #: <input type="text"/> | | | |
| As of date: <input type="text"/> | | | | Whsl. Code #: <input type="text"/> | | | |
| | | | | Fineline Code: <input type="text"/> | | | |
| Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE. | | | | | | | |
| *Please provide any additional information on page 2. | | See new p. 3 for Designated Drop Ship Only. | | Signature: <input type="text" value="Narender Chamala"/> | | | |