

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

Version 2021						Introduction 1	Type: Ne	w Item		Final Version			Date:	24.06	.2023	
			PRODUCT INFORMATION	ON						SPECIAL HAND	LING AND STOR	RAGE REQUI	REMENTS*			
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 Controlled Room – between 20 and 25 C (68° – 77° F)						
Medical Device Class, if applical																
DUNS:									*	ther Temperature Range F	Requirement					
Proprietary Name (If Applicable) a	and Established Na	ame: Plerixa	for Injection						]	(write in)						
Selling Unit NDC:	55150-356-01		Unit of Use NDC:		55150-356-01	UPC:	355150356010		N	otes						
UDI			CVX Code:			MVX Code:										
Description:	Plerixafor Injection	n 24 mg per 1.2 mL (	ls	this product to be shipped	I to customers on	ice?		No								
									ls	this product to be shipped	I to customers on	dry ice?		No		
Active Ingredient(s):  Plerixafor Injection																
	1	mperature excursion qu	estions:													
URL for Additional Product Inform	279 Princeton-Hightstown Road					Address 2:				ame:						
Address: City:	East Windsor	nisiown Road		State: NJ Zip: 08520				-	umber: roup E-mail:							
Key Contact:	Last Willuson			Email: Fax: 732-355-9449					iroup E-iliali.							
Phone Number:	888-238-7880							c. Special regulations for product in any states?								
Product Therapeutic Classification			1				Special requirements for this product?				No					
Trouble morapound classification		poolal rotarrio roquil ornoni	o for time product.			110	1									
	d. Store product	t (unit of sale) upright?														
ADDITIONAL PRODUCT INFORMATION  The product is?  Is the Product						PRODUCT DESCRIPTION INFORMA			Protect product (unit of sale) from light?							
a legend device?			Is the Product				1 Vial		e. Shelf life:	rotect product (unit or se	ile) iroin light:				Months	
if yes, enter class #			Orphan Drug Status			Size:				nitial shelf life at launch (	if different):				Months	
a product kit?			, i j			Strength:	24 mg per 1.2 mL			,	,					
if yes, list NDCs of			FDA Approval Status	)			ORDER INFORM	MATION								
component parts						Dosage Fori	Injection (Lie	quid)								
reverse numbered?						Dosage i on				nit of Sale			NDC selling			
co-licensed?			Allergens Present						_	Bottle			/ial (55150-3	•		
latex-free?						Product Sha	Vial Pack		-	x Box/Carton		(Write-in, e	e.g. 1 Box of 1	0 Vials)		
preservative-free? correctional institution block?									_	Ampule		Minimore		ا م		
opioid?						Product Col	or:			Glass Tube		winimum c	order quantit	y r		
Cannabinoid?			Country of Origin	India						Vial Liquid Sgl						
If Unit Dose, is item bar coded to u	unit dose for		Country of Origin			Product Imp	orint:			Vial Liquid Multi		If Yes, how	many of wh	ich package	type?	
hospital scanning?  Is this product covered under the										Vial Powder Sql		, ,	Each		71.	
If Unit Dose, indicate NDC here:  Trade Agreements Act (TAA)?  No										Vial Power Multi			Inner/Cartor	/Pack		
										Other: Write In			Case			
FOR GENERIC DRUG PRODUCTS																
Authorized Generic *If Authorized Generic, other									PHARMACY ORDER / BILL UNIT							
I. Orange Book Rating:					section fields are not applicable				Rec. sell unit to			Rx billing u	init to pharm	асу:		
II. Generic Equivalent to What Brand?:									1 Vial			Х	7 2001			
			COLLAIN OF CURITY ACT (D	000A) INEO	DMATION				(Write-in, e.g. 1	Vial)			Gram			
		DRUG SUPPLY	CHAIN SECURITY ACT (D	SCSA) INFO	RMATION							X	Milliliter			
Does supplier meet DSCSA defin	ition of manufactu	rer?	Yes	1	GLN:					ITEM	AND PACKING I	NFORMATIO	N			
Is product exempt from DSCSA?		<u> </u>	No	1												
If yes, select exemption:				_	GCP:				il		Dimone	ions (US msr	mts.)	Volume	Saleable #	
Other exemption - Write in:					JJI .				1	Weight Lbs.	Depth	Width	Height	(Cube)	Pieces	
Is product repackaged?			No		If yes, was or	iginal product			Item/Each:	0.00	·				4	
Is product sold by manufacturer's	s exclusive distrib	utor?	No	1		rect from mfr?				0.06	1.81	1.65	3.35	10.004775	1	
Has FDA granted waiver/exceptio			No		Provide source	ce manufacturer f	for repackaged pro	duct	Box/Carton/Bun	dle/ 0.949	11.65	3.78	4.33	190.68021	12	
If yes, attach documentation fro	om FDA.								Inner Pack:	0.949	11.00	3.70	4.00	130.00021	12	
									Case:	4.897	12.598	8.465	9.843	1049.6779	48	
		GTIN	AND HIBCC PRODUCT INF	ORMATION										S€a.0031∠.		
Colorbio Hoit of Marrows	0		LUDOO		OTIN	1.44	11-20-611-	OTINI 44	Pallet:	Sea: 346.456	48	40	Sea:46.34	8	Sea:3072	
Saleable Unit of Measure	S	aleable Quantity	HIBCC		GTIN 0035	N-14 55150356010	Unit of Use	e GTIN-14		Air: 424.814			Air: 54.61	Δir·104851	Air:3840	
x   Item/Each   x   Box/Carton/Bundle/Inner Pack	1 12 303551								COST INFORMATION				WHOLESALER USE ONLY:			
x Case						5150356015								JJ_GNI		
X Pallet		3840				5150356019	1		Regular Cost			Vendor #:				
							1		Invoice Cost (W	AC) (\$)		Whsl. Code	e #:			
									]]			Fineline Co	ode:			
	_								As of date:							
П																
			Attach copy of SAFETY DATA	SHEET (SD	S) or non hazard									<b>O</b> 1		
*Please provide any additional in	tormation on page	2.				See new p. 3 for	r Designated Drop	Ship Only.	S	ignature:			Narender	Chamala		