

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

Version 2021					Introduction T	Гуре:	New Item		X	Final Version			Date:	29.05	5.2023	
			PRODUCT INFORMATION							SPECIAL HAND	LING AND STOR	AGE REQU	REMENTS*			
Company Name:	Eugia US LLC				Applicat	tion:	ANDA	a. Temperatu	re – Indica	te the USP temper	ature range for t	his product	1			
Application Number for NDA/AN		/IA/510(k)(med dev	vice):								Controlled Room	-		3° – 77° F)		
Medical Device Class, if applicat	ble:															
DUNS:									Other Ten	nperature Range R	equirement					
Proprietary Name (If Applicable) a		me:							(writ Notes	e in)						
Selling Unit NDC:	55150-391-01		Unit of Use NDC:	55150-391-01 UPC: 355150391011 MVX Code:				Discard unused portion								
UDI			CVX Code:		WIVA Code.	MVX Code:									7	
Description:	Bendamustine Hyd	drochloride for Injec	tion, USP 25 mg per Vial							duct to be shipped				No	-	
Active Ingredient(s):									is this pro	duct to be shipped	to customers on c	iry ice?		No	_	
Active ingredient(s).								b. Contact fo	r temperati	ure excursion que	stions:					
URL for Additional Product Inform						Name:	and categories que									
Address:	279 Princeton-High	ntstown Road		Address 2:					Number:							
City:	East Windsor		State:	NJ Zip : 08520			Group E-	mail:								
Key Contact:	000 000 7000			Email:	722 255 0440								.			
Phone Number:	888-238-7880	l		Fax:	732-355-9449			c. Special reg		or product in any s				No	-	
Product Therapeutic Classificatio	on:								Special re	turns requirements	for this product?			No		
	ADDITIO	NAL PRODUCT IN	JEORMATION		PRODUCT	DESCRI	PTION INFORMATION	l d Store prod	uct (unit of	feala) unright?					1	
The made deat is 2	ADDITIO	MALTRODUCTII			1 Single-		THON IN ORMATION	i i d. Store prod	oduct (unit of sale) upright?						1	
The product is? a legend device?			Is the Product				1 Single-Dose Vial	e. Shelf life:	Protect p	rotect product (unit of sale) from light?					24 Months	
if yes, enter class #			Orphan Drug Status		Size:		1 Olligio Bood viai		Initial she	elf life at launch (if			Months			
a product kit?					04		25 mg per Vial			(
if yes, list NDCs of			FDA Approval Status		Strength:				ORDER INFORMATION							
component parts					Dosage Form:		Solution			_						
reverse numbered?			Allower Brown						Unit of Sa	a le Bottle		What is the NDC selling		-		
latex-free?			Allergens Present				Vial Pack			Box/Carton	1 Box of 1 Vial (55150-391-01)					
preservative-free?					Product Shape:		VIAIT CON		Ampule			(VVIIIC-III, C	(Write-in, e.g. 1 Box of 10 Vials)			
correctional institution block?					Due do et Cele					Glass		Minimum order quantity?		<i>i</i> ?		
opioid?					Product Cole	or:				Tube						
Cannabinoid?			Country of Origin India		Product Imp	orint:				Vial Liquid Sgl						
If Unit Dose, is item bar coded to unit dose for										Vial Liquid Multi Vial Powder Sql			many of whi	ch package	type?	
hospital scanning? Is this product covered under the Trade Agreements Act (TAA)?				No					X Each Inner/Carton/Pack							
If Only Dose, Indicate NDC here:										Vial Power Multi Other: Write In			Case	rack		
			FOR GENERIC DRUG PRODUCTS					<u>, </u>]			
								7	L							
				Au	thorized Generic		norized Generic, other			PHA	RMACY ORDER	/ BILL UNIT				
I. Orange Book Rating:						section	n fields are not applicable	Rec. sell unit	to custom	er?	Rx billing unit to pharmacy:					
II. Generic Equivalent to What Brand?:								1 Vial					x Each			
								(Write-in, e.g	. 1 Vial)				Gram			
		DRUG SUPPI	LY CHAIN SECURITY ACT (DSCSA) INFO	JRMATION								Х	Milliliter			
Does supplier meet DSCSA defini	ition of manufactur	rer?	Yes	GLN:						ITEM A	AND PACKING IN	NFORMATIO	N			
Is product exempt from DSCSA?			No													
If yes, select exemption:				GCP:]		Wainht I ba	Dimensi	ons (US msı	nts.)	Volume	Saleable #	
Other exemption - Write in:										Weight Lbs.	Depth	Width	Height	(Cube)	Pieces	
Is product repackaged?			No		iginal product			Item/Each:		0.0835	1.81	1.65	3.34	9.97491	1 Vial	
Is product sold by manufacturer's			No	•	rect from mfr?		decedes to t	De 10: 1 :-)							
Has FDA granted waiver/exception If yes, attach documentation from		oduct?		Provide sour	ce manufacturer fo	or repac	ckaged product	Box/Carton/E	sunale/	1.243	11.6	3.77	4.33	189.35956	12 Vials	
ii yes, attacii documentation no	mii DA.							Case:								
		GT	IN AND HIBCC PRODUCT INFORMATION	N				1		6.131	12.598	8.464	9.842	1049.4473	48 Vials	
								Pallet:		Air-425.424	48	40	Air-54.21	104083.2	Vials	
Saleable Unit of Measure	Sa	aleable Quantity	HIBCC		N-14	_	Unit of Use GTIN-14			Sea-523.520	40	40	Sea-44.37	104063.2 Sea-	Viais Sea-3072	
x Item/Each		1			55150391011				- COOT	INFORMATION			WHOLEGAL	ED LICE ON	V	
X Box/Carton/Bundle/Inner Pack X Case		48			55150391012 55150391016				COST	INFORMATION			WHOLESALI	ER USE UNL	- A-	
X Case Pallet		3840			55150391010	-		Regular Cost		Г		Vendor #:				
A Fallet 5040					0100001010			Invoice Cost				Whsl. Code #:				
									,			Fineline Co	Code:			
								As of date:								
			AH	(DC)		INIOEES	T LADEL AND DUCTO CO		A CINIO .	DADOODE						
			Attach copy of SAFETY DATA SHEET (S	or non hazar (כעו	u letter, PACKAGE	INSER	I, LABEL AND PHOTO OF F	-KUDUCI PACK	AGING and	DAKCUDE.						



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			PRODUCT INFORMATION							SPECIAL HAND	LING AND STOR	RAGE REQUI	REMENTS*			
Company Name:	Eugia US LLC				Applicat	tion:	ANDA	a. Temperatu	re – Indicat	e the USP tempe	rature range for t	this product.				
Application Number for NDA/AN		1A/510(k)(med dev	vice):						Temperatu		Controlled Room	-		3° – 77° F)		
Medical Device Class, if applicat	ble:															
DUNS:									Other Tem	perature Range R	equirement					
Proprietary Name (If Applicable) a									(write	e in)						
Selling Unit NDC:	55150-392-01		Unit of Use NDC:	55150-392-01 UPC: 355150392018				Discard unused portion								
UDI			CVX Code:		WIVA Code.	MVX Code:									1	
Description:	Bendamustine Hyd	rochloride for Injec	tion, USP 100 mg per Vial						-	duct to be shipped				No		
Active Ingredient(s):									is this prod	duct to be shipped	to customers on c	ary ice?		No		
Active ingredient(s).								b. Contact fo	r temperatu	re excursion que	estions:					
URL for Additional Product Information:									Name:	4						
	279 Princeton-High	tstown Road		Address 2:					Number:							
City:	East Windsor			State:	NJ Zip : 08520				Group E-r	mail:						
Key Contact:	888-238-7880		Email:	732-355-9449			a Smaaial raa	latiana fa		No			_			
Phone Number:				Fax:	732-333-9449			c. Special reg		r product in any			No	-		
Product Therapeutic Classificatio	on:								Special re	turns requirements	for this product?			No		
	ADDITIO	NAL PRODUCT IN	NEORMATION		PRODUCT (DESCRIE	PTION INFORMATION	d Store prod	luct (unit of	sale) upright?					1	
The product is?	7,55,1113		Is the Product					u. Gloro prod	•							
a legend device?			Is the Product				1 Single-Dose Vial	e. Shelf life:	Protect pi	rotect product (unit of sale) from light?					24 Months	
if yes, enter class #			Orphan Drug Status		Size:		g.c 2 000 1.a		Initial she	If life at launch (if	different):			Months		
a product kit?					Ctuom mth.		100 mg per Vial			•						
if yes, list NDCs of			FDA Approval Status		Strength:				ORDER INFORMATION							
component parts					Dosage Form:		Solution					Mile of the MDO and the second of				
reverse numbered?	verse numbered?		Allergene Present						Unit of Sa	ile Bottle		What is the NDC selling 1 Box of 1 Vial (55150-39)				
latex-free?							Vial Pack		X Box/Carton			(Write-in, e.g. 1 Box of 10 Vials)				
preservative-free?					Product Shape:				Ampule			(White-in, e.g. 1 box of 10 vials)				
correctional institution block?					Product Cole	Product Color:			Glass			Minimum order quantity?				
opioid?					1 Todact Con	oi.				Гube						
Cannabinoid?			Country of Origin India		Product Imp	rint:				/ial Liquid Sgl		16 1/2 - 1			0	
If Unit Dose, is item bar coded to unit dose for										/ial Liquid Multi /ial Powder Sql			many of wh	ich package	type?	
hospital scanning? Is this product covered under the Trade Agreements Act (TAA)?				No					X Each Inner/Carton/Pack							
II STILL BOSS, III GIGAGO TABO TIGIS.			3 ()	110						/ial Power Multi Other: Write In			Case	,,, aon		
			FOR GENERIC DRUG PRODUCTS										-			
				Au	thorized Generic		orized Generic, other	PHARMACY ORDER / BILL UNIT								
I. Orange Book Rating:			section	fields are not applicable	Rec. sell unit to customer?					Rx billing unit to pharmacy:						
II. Generic Equivalent to What Brand?:									x Each							
	ORMATION				(Write-in, e.g	. 1 Viai)			Gram Milliliter							
		B1(00 001 1 1	LY CHAIN SECURITY ACT (DSCSA) INFO	J. C.								^	_ William Co			
Does supplier meet DSCSA defini	ition of manufactur	er?	Yes	GLN:						ITEM .	AND PACKING IN	NFORMATIO	N			
Is product exempt from DSCSA?			No													
If yes, select exemption:				GCP:						Weight Lbs.	Dimensi	ons (US msr	•	Volume	Saleable #	
Other exemption - Write in:			N							vigiit Ebb.	Depth	Width	Height	(Cube)	Pieces	
Is product repackaged?	a avaluabra distrib	tor2	No		iginal product rect from mfr?			Item/Each:		0.178	2.16	2.16	4.33	20.202048	1 Vial	
Is product sold by manufacturer's Has FDA granted waiver/exception			No	•	rect from mfr? ce manufacturer fo	or range	kaged product	Box/Carton/E	Sundle/							
If yes, attach documentation from	•	oudot:		i iovide soul	oo manaracturer 10	or repac	magoa product	Inner Pack:	- 411410/	2.551	9.48	7.32	5.31	368.48002	12 Vials	
, , , , , , , , , , , , , , , , , , , ,								Case:		11.931	15.551	10.433	11.811	1916.259	48 Vials	
		GTI	IN AND HIBCC PRODUCT INFORMATION	N							15.551	10.433				
								Pallet:		Air-390.973	48	40	Air-52.24	100300.8	Vials	
Saleable Unit of Measure	Sa	aleable Quantity	HIBCC		N-14 55150392018		Unit of Use GTIN-14			Sea-510.284			Sea-40.43	Sea	Sea-1440	
x Item/Each Box/Carton/Bundle/Inner Pack		1 12			55150392018				COST	INFORMATION			WHOLESAL	ER USE ONL	Y:	
x Case		48			55150392013					JRIMATION			OLLUAL	LA COL ONL		
x Pallet 1920					55150392017			Regular Cost	t				Vendor #:			
								Invoice Cost				Whsl. Code #:				
						-		, , , , ,				Fineline Co	ode:			
	-					-		As of date:				-				
<u> </u>			Attach copy of SAFETY DATA SHEET (S	DS) or non hazar	d letter PACKAGE	INISERT	I LAREL AND PHOTO OF F	PRODUCT PACK	AGING and	BARCODE		1				
			Allach cody of safe it that a speer is													