

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

Version 2021						Introduction T	ype: New Item			Final Version			Date:	09.05	5.2023			
			PRODUCT INFORMATION							SPECIAL HAND	LING AND STOR	RAGE REQUI	REMENTS*					
Company Name: Eugia US LLC							ion: ANDA	а. Т	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	Medical Device Class, if applicable:																	
DUNS:									Other <sup>-</sup>	Temperature Range F	Requirement							
Proprietary Name (If Applicable) a		ame:								write in)								
Selling Unit NDC:	55150-313-01		Unit of Use NDC:	55	5150-313-01	UPC:	355150313013		Notes									
UDI			CVX Code:			MVX Code:												
Description:		Is this	product to be shipped	to customers on	ice?		No											
										product to be shipped	to customers on	dry ice?		No				
Active Ingredient(s):																		
UPL for Additional Product Information.										rature excursion qu	estions:							
URL for Additional Product Information: Address: 279 Princeton-Hightstown Road						Address 2:			Name									
City:	East Windsor			State: NJ Zip: 08520				Number: Group E-mail:										
Key Contact:				Email:		<b>2.</b> p. 00020		0.044										
Phone Number:	888-238-7880				Fax:	732-355-9449		c. S	c. Special regulations for product in any states?									
Product Therapeutic Classification	on:								Special requirements for this product?									
·			•	•	·				1									
	TION d. S	Store product (uni	t of sale) upright?					]										
The product is?			Is the Product						Protect product (unit of sale) from light?									
a legend device?			Is the Product			0:	1 Multi Dose Vial	e. S	Shelf life:	(	3			24	Months			
if yes, enter class #			Orphan Drug Status			Size:			Initial	shelf life at launch (	if different):				Months			
a product kit?						Strength:	400mg per 10mL				ORDER INFORMATION							
if yes, list NDCs of			FDA Approval Status		ou ongui.													
component parts					Dosage Form	Solution			Miles Company									
reverse numbered?									Unit of Sale What is the NDC selling unit?  Bottle 55150-313-01									
co-licensed? latex-free?	Allergens Present								x Box/Carton (Write-in, e.g. 1 Box of 10 Vi					Λ \/iale\				
preservative-free?						Product Sha	pe:		Ampule (Write-in, e.g. 1 Box of 10 Viais)									
correctional institution block?										Glass		Minimum o	rder quantit	v?				
opioid?						Product Color: Tube								•				
Cannabinoid?			Country of Origin Inc	dia		Product Imprint: Vial Liquid Sgl												
lf Unit Dose, is item bar coded to ເ	unit dose for					i roduct iiiip	11114.			Vial Liquid Multi				ich package	type?			
hospital scanning?			Is this product covered under							Vial Powder Sql			Each					
If Unit Dose, indicate NDC here:  Trade Agreements Act (TAA)?  No										Vial Power Multi			Inner/Carton	ı/Pack				
										Other: Write In			Case					
			FOR GENERIC DRUG PRODU	CTS														
					Δutk	norized Generic	*If Authorized Generic, otl	her		PH/	ARMACY ORDER	/ BILL LINIT						
I Ones are Be als Bettin as					Auti	iorized Gerieric	section fields are not appl	licable	Rec. sell unit to customer? Rx billing unit to pharmacy:									
I. Orange Book Rating:  II. Generic Equivalent to What Brand?:							•	Rec	Each					iacy:				
II. Generic Equivalent to What Brand :								T w	(Write-in, e.g. 1 Vial)				Gram					
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION								,	, 3 ,				Milliliter					
Does supplier meet DSCSA defin		rer?	Yes	G	iLN:					ITEM	AND PACKING II	NFORMATION	N					
Is product exempt from DSCSA?			No															
If yes, select exemption:				G	CP:					Weight Lbs.		ons (US msn	•	Volume	Saleable #			
Other exemption - Write in:			No			ainal aradess			m/Each:	<b>J</b>	Depth	Width	Height	(Cube)	Pieces			
Is product repackaged? Is product sold by manufacturer's	e avalueiva dietrik.	ıtor?	No No			ginal product ect from mfr?		liten	m/Each:	0.08506	1.42	1.42	2.56	5.162	1 vial			
Has FDA granted waiver/exception			INO	-			or repackaged product	Box	x/Carton/Bundle/									
If yes, attach documentation fro		oudot.			TOTIGO SOGIO	o manaraotaron n	or republicaged product		ner Pack:	5.7641	15.2	9.49	2.99	431.302	60 vials			
<b>,</b> ,								Cas	ise:	05.0000	00.070	45.045	7.077	0457.000	040:-1-			
		GTIN	AND HIBCC PRODUCT INFOR	RMATION						25.6002	20.079	15.945	7.677	2457.866	240 vials			
								Pall	llet:	Air-801.0456	48	40	51.06.39	Sea-	vials Sea-			
Saleable Unit of Measure	Sa	aleable Quantity	HIBCC		GTIN		Unit of Use GTIN	I-14		Sea-673.0446	-10	10	Sp2-13 30	833U8 8	6000			
X Item/Each	1 00355150313013 ack 60 30355150313014								COST INFORMATION									
X Box/Carton/Bundle/Inner Pack								COST INFORMATION					WHOLESALER USE ONLY:					
X Case Pallet		7200				5150313018 5150313012			gular Cost			Vendor #:						
X Pallet	П	1200			1035	0 1000 100 12			gular Cost /oice Cost (WAC) (	(\$)		Whsl. Code	#-					
	+						-	""	. 5.55 5551 (1776) (	(*)		Fineline Co						
	1						1	As o	of date:									
	1						1											
			Attach copy of SAFETY DATA SH	HEET (SDS)	or non hazard	letter, PACKAGE	INSERT, LABEL AND PHO	OTO OF PRODU	UCT PACKAGING	and BARCODE.								
*Please provide any additional in	formation on page	2.				See new p. 3 for	Designated Drop Ship O	Only.	Signat	ture:			D.Venkata Su	ırender Redd	ly			



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

Version 2021						Introduction T	ype: New Ite	em		Final Version			Date:	09.05	5.2023		
			PRODUCT INFORMATION	N						SPECIAL HAND	LING AND STOR	RAGE REQUI	REMENTS*				
Company Name: Eugia US LLC							ion: AND	Α	a. Temperature – Inc	this product.	oduct.						
Company Name: Eugia US LLC Application: ANDA Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):										a. Temperature – Indicate the USP temperature range for this product.  Temperature Range  Controlled Room – between 20 and 25 C (68° – 77° F)							
Medical Device Class, if applical		, ,,	,						1	, and the second				,			
DUNS:									Other	Temperature Range F	Requirement						
Proprietary Name (If Applicable) a	and Established Na	me:								(write in)							
Selling Unit NDC:	55150-314-01		Unit of Use NDC:		55150-314-01	UPC:	355150314010		Notes	3							
UDI			CVX Code:			MVX Code:											
Description:	Methylprednisolone	e Acetate Injectable	Is this	product to be shipped	to customers on	ice?		No	1								
										product to be shipped	to customers on	dry ice?		No			
Active Ingredient(s):																	
	·	erature excursion qu	estions:														
URL for Additional Product Information:							1		Name								
Address:	279 Princeton-High		Address 2:  State: NJ Zip: 08520				Number: Group E-mail:										
City: Key Contact:	East Windsor				Email:	NJ <b>Zip</b> : 06520			Grou	p E-maii:							
Phone Number:	888-238-7880				Fax:	732-355-9449			c Special regulation	ns for product in any	states?				1		
Product Therapeutic Classification					- I dx.	702-000-0440			-	al returns requirement		+2					
Froduct Therapeutic Classification	л.	Speci	ai returns requirement	s for this product?				1									
	ADDITIO	NAL PRODUCT INF	d. Store product (ur	nit of sale) unright?													
The war heat in 0	ADDITIO	NALT RODUCT IN				TROBOOTE	DESCRIPTION INFORM	ATION			ala) farana Balato				1		
The product is?			Is the Product				1 Multi Dose Via	.		ect product (unit of sa	ale) from light?			0.4	Months		
a legend device? if yes, enter class #			Is the Product Orphan Drug Status			Size:	I Wulli Dose via	al	e. Shelf life:	l shelf life at launch (	if difforant):			24	Months		
a product kit?			Orphian Drug Status				400mg per 5mL		IIIIIa	i Sileli ille at laulicii (	ii dillerent).				WOITTIS		
if yes, list NDCs of			FDA Approval Status			Strength:	Toomig por ome			ORDER INFORMATION							
component parts			. эттергота отшио				Solution										
reverse numbered?						Dosage Forr	orm:		Unit	of Sale		What is the	NDC selling	unit?			
co-licensed?	Allergens Present							•		Bottle		55150-314-01					
latex-free?						Product Sha	ne.		x Box/Carton (Write-in, e.g. 1 Box of 10 Vials)								
preservative-free?						1 Toduct Sila	pe.		Ampule								
correctional institution block?						Product Col	or:			Glass		Minimum o	rder quantit	y?			
opioid?						Tube											
Cannabinoid?			Country of Origin	India		Product Imp	rint:		Vial Liquid Sgl Vial Liquid Multi  If Yes, how many of which package typ								
If Unit Dose, is item bar coded to ι hospital scanning?	unit dose for		Is this product covered und	or the										ісп раскаде	type?		
If Unit Dose, indicate NDC here:			Trade Agreements Act (TA		No					Vial Powder Sql Vial Power Multi		X	Each Inner/Cartor	/Pack			
If Unit Dose, Indicate NDC here:										Other: Write In			Case	/I dok			
			FOR GENERIC DRUG PROD	LICTS						Other: White in			Jouse				
			TOR GENERIO BROOT ROD	0010					-								
					Aut	horized Generic	*If Authorized Generic,	other		PH/	ARMACY ORDER	/ BILL UNIT					
I. Orange Book Rating:							section fields are not a		Rec. sell unit to cus				nit to pharm	3CV:			
II. Generic Equivalent to What Brand?:									100. Son ann to sas	tomor.	1	Rx billing unit to pharmacy:  Each					
ii. Generic Equivalent to What Brand:									(Write-in, e.g. 1 Vial)				Gram				
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORM													Milliliter				
									7				4				
Does supplier meet DSCSA defin				ITEM	AND PACKING II	NFORMATIO	1										
Is product exempt from DSCSA?			No														
If yes, select exemption:					GCP:					Weight Lbs.	Dimensi	ions (US msn	nts.)	Volume	Saleable #		
Other exemption - Write in:										weight LDS.	Depth	Width	Height	(Cube)	Pieces		
Is product repackaged?			No		If yes, was ori				Item/Each:	0.07606	1.42	1.42	2.56	5.162	1 vial		
Is product sold by manufacturer's			No		•	ect from mfr?		_									
Has FDA granted waiver/exception		oduct?			Provide source	e manufacturer f	or repackaged product	t	Box/Carton/Bundle/	5.2241	15.2	9.49	2.99	431.302	60 vials		
If yes, attach documentation fro	om FDA.								Inner Pack:								
		GTIN	AND HIBCC PRODUCT INFO	ORMATION					Case:	23.4402	20.079	15.945	7.677	2457.866	240 vials		
		GIIN	AND HIBCC PRODUCT INTO	JAMATION					Pallet:	Air-736.2456			AII-	AII-90033.Z	AII-1200		
Saleable Unit of Measure	Sa	aleable Quantity	HIBCC		GTIN	I-14	Unit of Use GT	ΓIN-14	l allet.	Sea-619.0446	48	40	51.06.39	Sea-	vials Sea-		
x Item/Each	0.6	1	. 11500		_	5150314010	31111 01 030 01						CP3-13 30	୪330୪ ୪	6000		
x Box/Carton/Bundle/Inner Pack									COST INFORMATION WHOLESALER USE ONLY:								
X Case		240				5150314015	1										
<b>X</b> Pallet		7200				5150314019	]		Regular Cost			Vendor #:					
									Invoice Cost (WAC)	(\$)		Whsl. Code	#:				
												Fineline Co	de:				
									As of date:								
							]										
<u> </u>																	
			Attach copy of SAFETY DATA	SHEET (SD	S) or non hazard												
*Please provide any additional in	formation on page	2.				See new p. 3 for	Designated Drop Ship	Only.	Signa	ature:			D.Venkata Su	render Redd	y		