

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

						Introduction Ty	/pe: Post Launch Change		Final Version			Date:	22.0	70.24
			PRODUCT INFORMAT	TION					SPECIAL HAND	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name:	Eugia US LLC					Applicati	on: ANDA	a. Temperatu	re - Indicate the USP tempe	rature range for t	his product.			
Application Number for NDA/AN		O(k): 209133						ui romporata		Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applica									, ,					
DUNS:	650498244								Other Temperature Range F	Requirement	Do not store	lyophilized p	owder above	25°C
Proprietary Name (If Applicable)	and Established N	ame: Ertapen	em for Injection						(write in)	•	(77°F).			
Selling Unit NDC:	55150-282-20		Unit of Use NDC:		55150-282-20	UPC:	355150282203		Notes					
UDI			CVX Code:		•	MVX Code:								
Description:	Ertanenem for Ini	ection, 1g/vial [Single-I	Onse Viall						Is this product to be shipped	to customers on in	ce?		No	1
2000	Z. taponom ioi inj	ootion, rg/viai [omgio i	5000 1101						Is this product to be shipped				No	
Active Ingredient(s):		ERTAPENEM MONO	OSODIUM (NON STERILE	:)										J.
3 (4,			,	,				b. Contact fo	r temperature excursion que	estions:				
URL for Additional Product Infor	mation:								Name:		Eugia US Co	stomer Serv	ce	
Address:	279 Princeton-Hig	htstown Road				Address 2:			Number:		888-238-788			
City:	East Windsor				State:	NJ	Zip: 08520		Group E-mail:		Customers	<u> ervice@Ει</u>	giaUS.com	1
Key Contact:					Email:									
Phone Number:	888-238-7880				Fax:	732-355-9449		c. Special reg	gulations for product in any	states?			No	
Product Therapeutic Classification	on:	ANTI-INFECTIVE							Special returns requirement	s for this product?			No	
												,		
	ADDITI	ONAL PRODUCT INF	ORMATION			PRODUCT D	ESCRIPTION INFORMATION	d. Store prod	luct (unit of sale) upright?				Yes	
The product is?			Is the Product	Direct-Ship (Only				Protect product (unit of sa	ale) from light?			No	1
a legend device?		No	Is the Product			Size:	10 Single-Dose Vials	e. Shelf life:	. ,	, ,			24	Months
if yes, enter class #			Orphan Drug Status			Size:			Initial shelf life at launch (i	if different):				Months
a product kit?		No	· -			Strength:	1 gm per vial		•	•				
if yes, list NDCs of			FDA Approval Status			Strength:				ORDER INFORM	IATION			
component parts						Dosage Form	. Powder							
reverse numbered?		No				Dosage i oilii	•		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						Bottle		1 Box of 10	/ials		
latex-free?		Yes				Product Shap	Vial Pack		x Box/Carton		(Write-in, e.	g. 1 Box of 1	Vials)	
preservative-free?		Yes				1 Todact Onap			Ampule					
correctional institution block?		No				Product Colo	r.		Glass		Minimum o	der quantity	?	Yes
opioid?		No				1 Todact Gold			Tube					
Cannabinoid?		No	Country of Origin	India		Product Impr	int:		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for					oddot iiiipi			Vial Liquid Multi		If Yes, how		ch package	type?
hospital scanning?														
			Is this product covered u						Vial Powder Sql			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (1		No				Vial Power Multi			Inner/Carton	/Pack	
If Unit Dose, indicate NDC here:			Trade Agreements Act (1	TAA)?	No								/Pack	
If Unit Dose, indicate NDC here:		F		TAA)?	No				Vial Power Multi			Inner/Carton	/Pack	
If Unit Dose, indicate NDC here:		F	Trade Agreements Act (1	TAA)?	No				Vial Power Multi Other: Write In		1	Inner/Carton	/Pack	
If Unit Dose, indicate NDC here:		F	Trade Agreements Act (1	TAA)?			*If Authorized Generic, other		Vial Power Multi Other: Write In	ARMACY ORDER	1	Inner/Carton	/Pack	
	AP	F	Trade Agreements Act (1	TAA)?			*If Authorized Generic, other section fields are not applicable	Rec. sell unit	Vial Power Multi Other: Write In	ARMACY ORDER	1 / BILL UNIT	Inner/Carton Case		
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Br.			Trade Agreements Act (1	TAA)?	Au			Rec. sell unit	Vial Power Multi Other: Write In	ARMACY ORDER	1 / BILL UNIT	Inner/Carton		
I. Orange Book Rating:		INVANZ® (ertapene	Trade Agreements Act (1	ODUCTS Merck Sharp & E	Au Dohme Corp			Rec. sell unit	Vial Power Multi Other: Write In PH/ to customer? 10 Vial	ARMACY ORDER	1 / BILL UNIT Rx billing u	Inner/Carton Case		
I. Orange Book Rating:		INVANZ® (ertapene	Trade Agreements Act (1	ODUCTS Merck Sharp & E	Au Dohme Corp			Nec. sen unit	Vial Power Multi Other: Write In PH/ to customer? 10 Vial 1 Vial)	ARMACY ORDER	1 / BILL UNIT Rx billing u	Inner/Carton Case nit to pharm Each		
I. Orange Book Rating: II. Generic Equivalent to What Br	and?:	INVANZ® (ertapener	Trade Agreements Act (1 FOR GENERIC DRUG PRO m for injection) 1 g/vial of N CHAIN SECURITY ACT (1	ODUCTS Merck Sharp & E	Aur Dohme Corp			(Write-in, e.g	Vial Power Multi Other: Write In PH/ to customer? 10 Vial 1 Vial) de:]	/ BILL UNIT Rx billing u	Inner/Carton Case nit to pharm Each Gram Milliliter		
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Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2024 For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

MATERIAL	HAZARD CLASSIFICATION and TRANSPORTATION				
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	SDS Hazard Classification				
Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? No Does the product label bear a CA Prop 65 warning? No	Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard				
c. Contact Hazard? d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP?	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level:				
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name	Is the product a NIOSH hazardous drug? If yes, indicate which:				
c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics				
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)					
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:				
Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)				
Is this a reportable quantity? No RQ Threshold: Is this a marine pollutant? Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below) Limited Quantity Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4)	REMS: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier: NO Phone: Phone: DEA #: NCPDP#: NPI #:				
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Registry:				
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone: Comments				
Is the Product Controlled Substance? Controlled by State(s)? ARCOS Reportable? Schedule No. No Controlled Substance Code Listed Chemical (List I or II) No If yes, indicate which: Is it a scheduled listed chemical product?: No	RETURN INSTRUCTIONS Contact tel. # if product received damaged: Is product returnable for credit: Yes				
CLASS OF TRADE RESTRICTION:	URL/Link to returns policy:				
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	https://eugiaus.com/policies/return-policy/				
Restricted to retail pharmacy only: No	Special regulations or returns requirements for this				
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) No	product in certain states? If so, which states? Other requirements? Comments?				
Comments:					
MISCELLA	NEOUS NOTES and/or Image of Product Barcode:				



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

Version 2024

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method f	or Designated Drop Ship Product	Standard Order Receipt and Processing				
Purchase orders may be accepted by:		Purchase order daily receipt cut off time by supplier				
a. EDI		Cut off time:				
b. Autofax	Fax Number:					
c. Fax	Fax Number:	Shipping lead time of PO: Hours D	Days			
d. Phone only	Phone No.:					
e. Supplier Web Site only	Site Address:	Ships same day for next day receipt:				
Minimum Order Quantity:		Ships for second day receipt:				
Supplier's Customer Service Number:		Ships regular ground for 3-10 days receipt:				
Contracted 3PL company / contact #:	Name:					
	Phone:					
Expedited Freight Char	rges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing				
Expedited freight fees billed with each order		Overnight receipt available:				
Drop Ship service fee billed with each order	:	PO Receipt cut off time:				
Drop Ship miscellaneous fees billed:		Days of week overnight is available: Monday	y			
Comments:		Tuesda	ıy			
		Wedne	sday			
		Thursda	ay			
		Friday				
		Priority Overnight receipt available:				
Clas	ss of Trade Restriction:	PO Receipt Cut off time:				
No restriction: Select VES if sold to retail ph	armacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:				
Restricted to retail pharmacy only:	armacy, nospitals, clinics and physician onices	PO Receipt Cut off time:				
Restricted to hospital, clinics, and physician	offices only:	Phone: Phone #:				
Restricted from US territories? (explain in co	·	Order receipt method: Fax: Fax #:				
Comments:		EDI:				
		Overnight Fees apply:				
		Other fees apply:				
Other Data Info	ormation Required to Process PO:	Return Instructions				
Patient Procedure Date:		Contact # if product is received damaged:				
Physician Name:		Is product returnable for credit:				
Physician/Clinic Phone #		URL/Link to returns policy:				
Physician State License #		Crta/Link to rotario ponoy.				
Physician/Clinic DEA #:		Special regulations or returns requirements for this product in certain states?				
Physician/Clinic Specialty:		If so, which states? Other requirements? Comments?				
	liscellaneous Notes:					
		ADDITIONAL INFORMATION				
		Is product order for scheduled patient procedure? Is product order for restocking purposes?				
		is product order for restocking purposes?				