

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

Version 2024						Introduction Type	: New Item		Final Version			Date:	9/8/2	:025
			PRODUCT INFORMAT	TION					SPECIAL HAND	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name:	MILLA PHARMAC	CEUTICALS INC				Application:	: ANDA	a. Temperature – Indica	te the USP tempe	rature range for th	is product.			
Application Number for NDA/ANI	DA/BLA; PMA/510	O(k): A207847	1				<u>'</u>			Controlled Room -		and 25 C (68	, – 77° F)	
Medical Device Class, if applicab	ole:							1	- '					
DUNS:	119319487							Other Ter	mperature Range R	Requirement				
Proprietary Name (If Applicable) a	nd Established Na	ame:							te in)					
Selling Unit NDC:	81284-0153-10		Unit of Use NDC:		81284-0153-0		1284153102	Notes						
UDI			CVX Code:			MVX Code:		1						
Description:	Pineracillin and T	azobactam for Injection	4a/0.5a 4.5a x 10					Is this pro	duct to be shipped	to customers on ic	e?		No	
Description.	r iporaoiiiir ana ri	azobaotam for injudaci.	igro.og nog x to							to customers on di			No	
Active Ingredient(s):		Piperacillin and Tazob	bactam					10 0.110 p. c	ouder to be empped	to odotomoro on di	<i>y</i> 100.			
								b. Contact for temperat	ure excursion que	estions:				
URL for Additional Product Inform	iation:							Name:			DL-QA GPI I	Pharma		
Address:	1310 Highway 968	E				Address 2: Sui	ite 104A	Number:						
City:	White Bear Lake				State:	MN Zi	ip: #55110	Group E-	-mail:		qa@gpipha	arma.ie		
Key Contact:	Siddharth Nirmal				Email:	siddharth.nirmal@	Paforallpharma.com							
Phone Number:	+1 302 946 0117				Fax:			c. Special regulations f	or product in any	states?			No	
Product Therapeutic Classification	n:							Special re	eturns requirements	s for this product?			No	
	ADDITI	IONAL PRODUCT INFO	ORMATION			PRODUCT DES	CRIPTION INFORMATION	d. Store product (unit o	f sale) upright?				No	
The product is?			Is the Product	Direct-Ship C	nlv	T		Protect of	product (unit of sal	le) from light?			No	
a legend device?		No	Is the Product	Unit of Use			10 vials	e. Shelf life:	(4	·-, ··g			24	Months
if yes, enter class #		1.10	Orphan Drug Status			Size:	1.0 1.1		elf life at launch (i	f different):				Months
a product kit?		No				24	4g/0.5g 4.5g			,				
if yes, list NDCs of			FDA Approval Status			Strength:	0 0 0			ORDER INFORM	ATION			
component parts						Danama Farmi	Injectable							
reverse numbered?		No				Dosage Form:		Unit of S	ale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						Bottle		1 box of 10 v	rials		
latex-free?		Yes				Product Shape:	NA		Box/Carton		(Write-in, e.	g. 1 Box of 10	Vials)	
preservative-free?		Yes				. roundt Griupor			Ampule					
correctional institution block?		No				Product Color:	NA		Glass		Minimum or	der quantity	?	Yes
opioid?		No							Tube					
Cannabinoid?		No	Country of Origin	Italy		Product Imprint:	NA		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for								Vial Liquid Multi				ch package t	ype?
hospital scanning?		Yes	Is this product covered un						Vial Powder Sql			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (Ta	AA)?	Yes				Vial Power Multi			Inner/Carton	Pack	
									Other: Write In		1	Case		
			FOR GENERIC DRUG PRO	DDUCIS										
						thorized Generic *If	Authorized Generic, other		DH	ARMACY ORDER	RILL LINIT			
	• •			_	Au		ction fields are not applicable	5		ARMAOT ORBERT				
I. Orange Book Rating:	AP						out in the depricable	Rec. sell unit to custom			Rx billing u	nit to pharma	cy:	
II. Generic Equivalent to What Brai	nd?:							1 box of 10 (Write-in, e.g. 1 Vial)	vials			Each		
		ZoSyn												
			CHAIN SECURITY ACT (F	DSCSA) INEOE	MATION							Gram		
			CHAIN SECURITY ACT (D	DSCSA) INFOR	RMATION			HCPCS J-Code:			x	Gram Milliliter		
Does supplier meet DSCSA definit	ion of manufactur	DRUG SUPPLY		DSCSA) INFOR		0381284000000			ITEM	AND PACKING IN		Milliliter		
Does supplier meet DSCSA definit	ion of manufactur	DRUG SUPPLY	CHAIN SECURITY ACT (D Yes	DSCSA) INFOR	RMATION GLN:	0381284000000			ITEM	AND PACKING IN		Milliliter		
Is product exempt from DSCSA?	tion of manufactur	DRUG SUPPLY	Yes	DSCSA) INFOR	GLN:	0381284000000			ITEM		FORMATION	Milliliter	Volume	Salaabla #
Is product exempt from DSCSA? If yes, select exemption:	tion of manufactui	DRUG SUPPLY	Yes	DSCSA) INFOR		0381284000000			ITEM Weight Lbs.	Dimensio	FORMATION	Milliliter		Saleable #
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	tion of manufactu	DRUG SUPPLY	Yes No	DSCSA) INFOR	GLN: GCP:		sod .	HCPCS J-Code:	Weight Lbs.	Dimensio Depth	FORMATION ons (US msm Width	Milliliter N nts.) Height	(Cube)	Saleable # Pieces
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?		DRUG SUPPLY	Yes No	DSCSA) INFOR	GLN: GCP: If yes, was or	iginal product purchas	sed			Dimensio	FORMATION	Milliliter		
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	exclusive distribu	DRUG SUPPLY	Yes No No Yes	DSCSA) INFOR	GLN: GCP: If yes, was or direct from m	iginal product purchas		HCPCS J-Code:	Weight Lbs.	Dimension Depth 1.67	ons (US msm Width	Milliliter N hts.) Height 3.03	(Cube) 8.450367	Pieces 1
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception	exclusive distribu	DRUG SUPPLY	Yes No	DSCSA) INFOR	GLN: GCP: If yes, was or direct from m	iginal product purchas		HCPCS J-Code: Item/Each: Box/Carton/Bundle/	Weight Lbs.	Dimensio Depth	FORMATION ons (US msm Width	Milliliter N nts.) Height	(Cube)	Pieces
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	exclusive distribu	DRUG SUPPLY	Yes No No Yes	DSCSA) INFOR	GLN: GCP: If yes, was or direct from m	iginal product purchas		HCPCS J-Code:	Weight Lbs. 0.11 1.46	Dimension Depth 1.67 8.58	ons (US msm Width 1.67 3.26	Milliliter N hts.) Height 3.03 3.54	(Cube) 8.450367 99.016632	Pieces 1
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Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

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For Designated Drop Ship Only Products, Please Use Page 3

MATE	RIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION		
Is this product (check all that apply):				
a. Cytotoxic?	No	SE	S Hazard Classification	
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?			_	
Is the product a CA Prop 65 carcinogen?	No	Organic	Corrosive	
Is the product a CA Prop 65 reproductive toxicant?	No	Inorganic	Oxidizer	
Does the product label bear a CA Prop 65 warning?	No	Steroid/Androgen x	Contact Hazard	
c. Contact Hazard?	Yes	Does the product have an Aerosol class? If yes, identify NFPA Storage Level:		
d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)	Yes	NFPA Storage Level:		
e. Does the product contain DEHP?	No	NFFA Storage Level.		
Is this product regulated for shipment by DOT?	No	Is the product a NIOSH hazardous drug?	No	
(if yes, answer a-e below and provide SDS) a. UN/Identification Number		If yes, indicate which:		
b. Proper Shipping Name				
c. DOT Hazard Class		Haza	rdous Waste Identification	
d. Packing Group		11020		
e. Inhalation Hazard?	Yes	EPA Hazardous Waste Code:		Waste Characteristics
Is this product regulated for shipment by IATA?	No			
(if yes, answer a-e below and provide SDS)	140	REMS.o	REGISTRY RESTRICTIONS	
a. UN/Identification Number		- NEMO O		
b. Proper Shipping Name		Is there a REMS on this product?	No	
c. DOT Hazard Class		If Yes, is it managed with a pharmacy registry?		
d. Packing Group		Website URL:	·	
e. Inhalation Hazard?	Yes			
Is the product restricted for air shipment? If so, indicate restriction:		Med Guide Required		
Passenger		Limited Distribution Requirement		
Cargo		Comments / Details: (For example, iPledge program?)		
Passenger & Cargo				
Is this a reportable quantity? No		REMS:		
RQ Threshold:		REMS Program Manager Name:		Phone:
Is this a marine pollutant? No		Supplier Manages REMS registry exclusively:		
Is this product shipped utilizing an authorized DOT exception or Special Permit?		Wholesale distributor support:		
No (if yes, identify method below)		Provider Name:		DEA #:
Limited Quantity		Site Enrollment Number assigned		NCPDP#:
Consumer Commodity, ORM-D		by Supplier:		NPI #:
Small Quantity (49 CFR 173.4) Special Permit; DOT-SP		Comments		
Special Provision (listed in Column 7 of 49 CFR 172.101);		Comments		
SP#		Registry:		
or#				Dhana
ADD'L STORAGE INFORMATION		Registry Program Contact Name: Comments		Phone:
Is the Product Controlled Substance? No Controlled Substance Code			ETURN INSTRUCTIONS	
Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II)	No	- N	TOWN INSTRUCTIONS	
ARCOS Reportable? No If yes, indicate which:	140	Contact tel. # if product received damaged:	773-541-3317	
Schedule No. Is it a scheduled listed chemical product?:	No	,	Yes	
CLASS OF TRADE RESTRICTION:		Is product returnable for credit: URL/Link to returns policy:	100	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Yes	www.millapharm	aceuticais.com	
Restricted to retail pharmacy only:	No	Special regulations or returns requirements for this		
Restricted to hospital, clinics, and physician offices only:	No	product in certain states?	No	
Restricted from US territories? (explain in comments)	No	If so, which states? Other requirements? Comments?		
Comments:				
	CELL ANEC	US NOTES and/or Image of Product Barcode:		
Wilso	PELLAINEU	OS 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 for Designated Drop Ship Product	Standard Order Receipt and Processing			
Purchase orders may be accepted by: a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:			
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing			
Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday			
	Priority Overnight receipt available:			
Class of Trade Restriction:	PO Receipt Cut off time:			
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:			
Other Data Information Required to Process PO:	Return Instructions			
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty: Miscellaneous Notes:	Contact # if product is received damaged: Is product returnable for credit: URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?			
	ADDITIONAL INFORMATION			
	Is product order for scheduled patient procedure? Is product order for restocking purposes?			