

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

Version 2024						Introduction T	ype: New Iter	em		Final Version			Date:	9/8/2	2025
			PRODUCT INFORMAT	ION						SPECIAL HAN	IDLING AND STOR.	AGE REQUIF	REMENTS*		
Company Name:	MILLA PHARMAC	EUTICALS INC				Applicati	ion: ANDA	Α	a. Temperature - Indi	cate the USP tempe	erature range for th	nis product.			
Application Number for NDA/ANI	DA/BLA; PMA/510	(k): A207848	3						Temper	rature Range	Controlled Room -	between 20	and 25 C (68	° – 77° F)	
Medical Device Class, if applicable:															
DUNS:	119319487									emperature Range I	Requirement				
Proprietary Name (If Applicable) a		ime:								rite in)					
Selling Unit NDC:	81284-0155-01		Unit of Use NDC:		81284-0155-0	0 UPC: MVX Code:	381284155014		Notes						
UDI			CVX Code:			WVX Code:									
Description:	Piperacillin and Ta	azobactam for Injection	, USP 36g/4.5g 40.5g x 1							product to be shipped				No	
Active Ingredient(s):		Piperacillin and Tazol							Is this p	product to be shipped	d to customers on di	ry ice?		No	
Active ingredient(s).		riperaciiiii and razol	Jaciaiii						b. Contact for temper	ature excursion qu	estions:				
URL for Additional Product Inform	nation:								Name:	ataro executeren qu		DL-QA GPI F	harma		
Address:	1310 Highway 96E					Address 2:	Suite 104A		Numbe	r:					
City:	White Bear Lake				State:	MN	Zip: # 55110		Group	E-mail:		qa@gpipha	arma.ie		
Key Contact:	Siddharth Nirmal				Email:	siddharth.nirm	al@aforallpharma.co	<u>om</u>							
Phone Number:	+1 302 946 0117				Fax:				c. Special regulations					No	
Product Therapeutic Classification: Special returns requirements for this product? No															
ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION d. Store product (unit of sale) upright?															
The was dead in 0	7,55111	5 <u></u>		Direct-Ship C	under .		2001 11011 01				-l-\ f l'-l-40				
The product is? a legend device?		No	Is the Product Is the Product	Unit of Use	rilly		1 vial		e. Shelf life:	t product (unit of sa	ale) from light?			No 24	Months
if yes, enter class #		INO	Orphan Drug Status	Offic of OSC		Size:	i viai			helf life at launch (if different):			24	Months
a product kit?		No				Ctue w mth.	36g/4.5g 40.5g			(
if yes, list NDCs of			FDA Approval Status			Strength:					ORDER INFORM	IATION			
component parts						Dosage Form	Injectable								
reverse numbered? co-licensed?		No No	Allamana Duacant						Unit of	Sale Bottle		What is the 1 vial	NDC selling	unit?	
latex-free?		Yes	Allergens Present				NA			Box/Carton		(Write-in, e.e	1 Boy of 1) Viale)	
preservative-free?		Yes				Product Shap	De:			Ampule		(**************************************	g. 1 DOX 01 1	, viais)	
correctional institution block?		No				Product Colo	". NA			Glass		Minimum or	der quantity	?	Yes
opioid?		No				Product Colo				Tube					
Cannabinoid?		No	Country of Origin	Italy		Product Impr	int: NA			Vial Liquid Sgl					_
If Unit Dose, is item bar coded to u	nit dose for	Vaa	la this was dust sourced up	al a u ála a		•				Vial Liquid Multi			many of whi Each	ch package t	ype?
hospital scanning? If Unit Dose, indicate NDC here:		Yes	Is this product covered un Trade Agreements Act (TA		Yes				x	Vial Powder Sql Vial Power Multi			Inner/Carton	/Dack	
ii Olit Dose, ilidicate NDC liere.			ridde rigicements riot (17	01):	163				^	Other: Write In			Case	/I ack	
			FOR GENERIC DRUG PRO	DUCTS											
					Au	thorized Generic	*If Authorized Generic, o			PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AP			1			section fields are not app	oplicable	Rec. sell unit to custo	mer?		Rx billing ur	nit to pharm	acy:	
II. Generic Equivalent to What Bra	nd?:	ZoSyn							1 vi	al			Each		
		DRUG GURRI V	OLIAIN OF OURITY A OT (D	OOOA) INFOE	MATION				(Write-in, e.g. 1 Vial)				Gram		
		DRUG SUPPLY	CHAIN SECURITY ACT (D	SCSA) INFOR	MATION				HCPCS J-Code:			X	Milliliter		
Does supplier meet DSCSA definit	tion of manufactur	er?	Yes	1	GLN:	0381284000000				ITEN	AND PACKING IN	FORMATION	١		
Is product exempt from DSCSA?			No	1											
If yes, select exemption:					GCP:						Dimensio	ons (US msm	its.)	Volume	Saleable #
Other exemption - Write in:										Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was or	iginal product purc	hased		Item/Each:	0.326	2.6	2.6	4.62	31.2312	1
Is product sold by manufacturer's			Yes		direct from m					0.320	2.0	2.0	4.02	31.2312	
Has FDA granted waiver/exception		oduct?	No		Provide source	ce manufacturer for	repackaged product		Box/Carton/Bundle/	0.529	2.75	5.11	2.75	38.644375	1
If yes, attach documentation from	n FDA.								Inner Pack: Case:						
		GTIN	AND HIBCC PRODUCT IN	FORMATION					Case.	15.192	14.96	6.61	14.96	1479.3286	25
		-							Pallet:	504.004	47.044	00.07	47.044	07070 004	000
Saleable Unit of Measure	RFID tag(Y/N)	Saleable	HIBCC		GTII	N-14	Unit of Use GTI	IN-14		591.004	47.244	39.37	47.244	87873.664	900
		Quantity													
Item/Each						81284155007	0038128415400	000		ST INCODES TO			MUOL EQ AL	TO LICE ON	V.
X Box/Carton/Bundle/Inner Pack X Case		25				81284155014 81284155018		-		ST INFORMATION			WHOLESAL	ER USE ONL	т.
x Case x Pallet		900			2030	01204100010			Regular Cost			Vendor #:			
									Invoice Cost (WAC) (\$	5)	\$69.00	Whsl. Code	#:		
												Fineline Cod	de:		
									As of date:	6/13/2022					
 		,	Attach copy of SAFETY DAT	A CHEET (CD	S) or non ha	rd letter DACKACE	INCEDT I ADEL AND DI	HOTO OF BD/	ODLICT DACKACING	nd BARCODE		<u> </u>			
*Please provide any additional info	ormation on page		nuacii copy oi SAFETT DAT	A SHEET (SD	o, or non naza		Designated Drop Ship O		ODUCT PACKAGING at						
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Version 2024

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?	SDS Hazard Classification								
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?									
Is the product a CA Prop 65 carcinogen?	Organic Corrosive								
Is the product a CA Prop 65 reproductive toxicant?	Inorganic	Oxidizer							
Does the product label bear a CA Prop 65 warning?	No	Steroid/Androgen x	Contact Hazard						
	Yes								
c. Contact Hazard?	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.)	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				Hazardous 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:	product in certain states?	No							
Restricted from US territories? (explain in comments)	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:							



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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?					