

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

Steel Stee	Version 2021						Introduction 7	Туре:	New Item		x	Final Version			Date:	2/27	/2023
Application Number for MANADOMENIA (Arright PANADOMENIA (Arright PANAD	PRODUCT INFORMATION								SPECIAL HAN	DLING AND STOF	RAGE REQUI	REMENTS*					
Application Human for NAMADOLALS, (Annal), PRANTONING CONTROLL (1972)	Company Name: Camber Pharmaceuticals, Inc. Application: ANDA																
DANSE Propriet P																	
Registration Margin Color Service Margin Color Service Margin Color	Medical Device Class, if applicab	ble:															
Service CV Code													Requirement				
Description Permissipation Action in Engineering (1) Anti-in preference (1) Anti-in prefere			ime: Amir		SP, 0.25 g/mL ((250 mg/ml) 23						e in)					
Description: Authorized Acid Child (State USER) - 20% gold.		31722-035-23						3317220	035231	+	Notes						
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Active registration of the product o	Description: Aminocaproic Acid Oral Solution USP, 0.25 g/mL															-	
URIS for Additional Product Informations Proceedings Proceedings Proceedings Address 2: State: Copy Proceedings Proceedings ACCITICATE PRODUCTS ACCITI	Active Ingradient(s): Aminocarpic Acid								is this product to be shipped to customers on dry ice:								
URL for Additional Product Informations Authorize 100 Contential Rev (and 30) Contenti										estions:							
District	URL for Additional Product Inform	nation:	www.camberpharm	na.com								•		Soma Raju			
They conduct is considered Services Email: Disable Classification: Variety 2018 Art Product Image and Classification: Variety 2018 Art Varie			Ave (and) 800 Cente	ennial Ave, Suite 1													
Phone Number: \$\$6627361 \$\$7255627361 \$\$7255627361 \$\$7255627361 \$\$7255627361 \$\$7255627361 \$\$\$7255627361 \$\$\$7255627361 \$\$\$\$7255627361 \$\$\$\$\$7255627361 \$										Group E-mail: somaraju@heterousa.com							
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The product Lay a lagend device? If yes, enter class #		ADDITI	ONAL PRODUCT I	NFORMATION			PRODUCT	DESCRIP	PTION INFORMATION	d Store proc	duct (unit of	sale) unright?				No	1
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Authorized Generic, other section fields are not applicable I. Orange Book Rating: I. Corange Book Rating: II. Generic Equivalent to What Brand?: Amicar				FOR GENERIC DRUG PR	ODUCTS					1					1		
I. Orange Book Rating: II. Generic Equivalent to What Brand?: AA Amicar																	
II. Generic Equivalent to What Brand?: Amicar Does supplier meet DSCSA definition of manufacturer?						Au	thorized Generic					PH	ARMACY ORDER	/ BILL UNIT			
Does supplier meet DSCSA definition of manufacturer? Yes GLN: 0331722000000 ITEM AND PACKING INFORMATION Milliliter	I. Orange Book Rating:	AA						section	fields are not applicable	Rec. sell unit	t to custome	er?		Rx billing u	nit to pharm	асу:	
Does supplier meet DSCSA definition of manufacturer? Yes GLN: 0331722000000	II. Generic Equivalent to What Bra	ınd?:	Amicar														
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If yes, select exemption: Other exemption - Write in: Is product repackaged? If yes, select exemption: Other exemption - Write in: Is product repackaged? If yes, was original product purchased Yes direct from mfr? Has FDA granted waiver/exception			DRUG SUPI	PLY CHAIN SECURITY ACT (DSCSA) INFOR	RMATION				Milliliter							
If yes, select exemption: Other exemption - Write in: Is product repackaged? If yes, select exemption: Other exemption - Write in: Is product repackaged? If yes, was original product purchased Yes direct from mfr? Has FDA granted waiver/exception	Does supplier meet DSCSA definit	tion of manufactur	er?	Yes	7	GI N:	0331722000000					ITEM	AND PACKING I	NEORMATIO	N		
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product resold by manufacturer's exclusive distributor? Has FDA granted waiver/exception/exemption for product? If yes, attach documentation from FDA. Saleable Unit of Measure Saleable Quantity HIBCC GTIN-14 Unit of Use GTIN-14 00331722035231							2202200000										
Other exemption - Write in: Is product repackaged? No If yes, was original product purchased Ves direct from mfr? Provide source manufacturer for repackaged product If yes, attach documentation from FDA. Saleable Unit of Measure Saleable Quantity HIBCC GTIN-14 O0331722035231	If yes select exemption:					GCP.				i			Dimensi	ons (US msn	nts.)	Volume	Saleable #
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Is product sold by manufacturer's exclusive distributor? Has FDA granted waiver/exception/exemption for product? If yes, attach documentation from FDA. Saleable Unit of Measure Saleable Quantity HIBCC GTIN-14 Unit of Use GTIN-14	Is product repackaged?							chased	Yes	Item/Each:		0.7	1				1
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Saleable Unit of Measure Saleable Quantity HIBCC GTIN-14 Unit of Use GTIN-14										Pallet:							
Box/Carton/Bundle/Inner Pack 20331722035235 COST INFORMATION WHOLESALER USE ONLY: X	Saleable Unit of Measure	S	aleable Quantity	HIBCC		GTI	N-14		Unit of Use GTIN-14							0	
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Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE. *Please provide any additional information on page 2 See new p. 3 for Designated Drop Ship Only Signature:	*Disease manufale dated		2	Attach copy of SAFETY DA	TA SHEET (SD	OS) or non haza				PRODUCT PACK	AGING and	BARCODE.					



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

Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MA	TERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply): a. Cytotoxic?	No	SDS Hazard Classification					
 b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? 	x 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?	No No	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level:	No				
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	No	Is the product a NIOSH hazardous drug? If yes, indicate which:	No				
c. DOT Hazard Class d. Packing Group		Hazardous Waste Identification					
e. Inhalation Hazard?	No	EPA Hazardous Waste Code:		Waste Characteristics			
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)	No	REMS o	r REGISTRY RESTRICTIONS				
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	No	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:	No				
Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	No	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? No Is this product shipped utilizing an authorized DOT exception or Special Permit? No (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: DEA #: NCPDP#: NPI #:			
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);		Comments					
SP#		Registry: Registry Program Contact Name:	No	Phone:			
ADD'L STORAGE INFORMATION		Comments		<u>'</u>			
Is the Product Controlled Substance? Controlled Substance Code Controlled by State(s)? ARCOS Reportable? Schedule No. No Is it a scheduled listed chemical product?:	No No	Contact tel. # if product received damaged: Is product returnable for credit:	1-866-827-3647 Yes				
CLASS OF TRADE RESTRICTION:		URL/Link to returns policy:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only:	Yes No	Special regulations or returns requirements for this	rvice@camberpharma.com				
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)	No No	product in certain states? If so, which states? Other requirements? Comments?	No				
Comments:	140						
MI	SCELLANEO	US NOTES and/or Image of Product Barcode:					



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

Version 2021

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

Order Method for Designated Drop S	nip Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI		Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	per:	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 Designa	ed Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order:		Overnight receipt available: PO Receipt cut off time:
Drop Ship miscellaneous fees billed: Comments:		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, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	s and physician offices	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to F	rocess PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:		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?
Miscellaneous Notes:		
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure? Is product order for restocking purposes?