

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

Version 2021						Introduction Type	e: New Item		x Final Version			Date:	3/20	/2024
			PRODUCT INFORMA	TION					SPECIAL H	ANDLING AND STO	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA					: ANDA	a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 216139								Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)						
Medical Device Class, if applicable:														
DUNS:	11-856-3719							_	Other Temperature Ran	je Requirement		permitted to 1	5° to 30°C	
Proprietary Name (If Applicable) a		me: Panto	prazole Sodium for Delayed		uspension 40 m				(write in)		(59° to 86°F	")		
Selling Unit NDC:	31722-032-32		Unit of Use NDC				1722032322		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Pantoprazole Sodi	ium for Delayed-Rel	ease Oral Suspension 40 mg	3					Is this product to be ship	ped to customers on	ice?		No	
									Is this product to be ship	ped to customers on	dry ice?		No	
Active Ingredient(s): Pantoprazole Sodium, USP										_				
IID for Additional Decision Information							b. Contact fo	or temperature excursion	questions:	Soma Raju				
URL for Additional Product Information: www.camberpharma.com Address: 1031 Centennial Ave (and) 800 Centennial Ave, Suite 1			Address 2:		-	Name: Number:		732-529-042	າາ					
City:	Piscataway	ive (and) 000 Cente	illiai Ave, Suite i		State:		ip: 08854	-	Group E-mail:			heterousa.com	m	
Key Contact:	Customer Service					customerservice@ca	amberpharma.com							
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special re	gulations for product in a	ny states?			No	1
Product Therapeutic Classification	n:	Proton pump inhibi	itor (PPI)						Special returns requirem	ents for this product?			No	
Openia realistic equication of any product.											1			
	ADDITIO	ONAL PRODUCT IN	NFORMATION			PRODUCT DES	SCRIPTION INFORMATION	d. Store product (unit of sale) upright?						
The product is?			Is the Product	Direct-Ship (Only				Protect product (unit o	sale) from light?			No	1
a legend device?		No	Is the Product	Unit Dose		Size:	30 unit dose packets	e. Shelf life:	, ,	, •			24	Months
if yes, enter class #			Orphan Drug Status			Size.			Initial shelf life at laund	h (if different):				Months
a product kit?		No				Strength:	40 mg							
if yes, list NDCs of			FDA Approval Status							ORDER INFORI	MATION			
component parts						Dosage Form:	Granules		Helt of Oak		\A/h a4 ia 4h a	NDC asilina		
reverse numbered? co-licensed?		No No	Allergens Present						Unit of Sale Bottle			NDC selling 30 Unit Dose		
latex-free?		Yes					N/A		x Box/Carton			g. 1 Box of 1		
preservative-free?		Yes	Cor	n, Nuts		Product Shape:	1071		Ampule		(vviite iii, e.	.g. 1 Dox 01 1	o viais)	
correctional institution block?		No				Beer devel Online	Pale yellow to brown		Glass		Minimum o	rder quantity	1?	Yes
opioid?		No				Product Color:	,		Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint	N/A		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	ınit dose for					T Toddot IIIIpi III			Vial Liquid Mu		If Yes, how		ich package	type?
hospital scanning?		Yes	Is this product covered						Vial Powder S		1	Each		
If Unit Dose, indicate NDC here:		31722-032-31	Trade Agreements Act (IAA)?	No				Vial Power Mu Other: Write In	ti		Inner/Cartor Case	n/Pack	
			FOR GENERIC DRUG PF	ODUCTO					Other: write in			Case		
			FOR GENERIC DRUG FF	ODUCIS										
					Au	thorized Generic *If	Authorized Generic, other			PHARMACY ORDER	R / BILL UNIT			
I. Orange Book Rating:	AB						ction fields are not applicable	Rec sell un	it to customer?		Py hilling u	nit to pharm	2CV:	
II. Generic Equivalent to What Bra		Protonix									TO DITTING O	Each	uoy.	
								(Write-in, e.g	g. 1 Vial)			Gram		
		DRUG SUPP	LY CHAIN SECURITY ACT	(DSCSA) INFO	RMATION							Milliliter		
		_		_										
Does supplier meet DSCSA definit	tion of manufacture	er?	Yes No	_	GLN:	0331722000000			II.	EM AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			INU											
If yes, select exemption:					GCP:				Weight Lbs		ions (US msr	•	Volume (Cube)	Saleable # Pieces
Other exemption - Write in: Is product repackaged?			No		If you was a	riginal product purcha	end	Item/Each:	-	Depth	Width	Height	(Cube)	
Is product repackaged? Is product sold by manufacturer's	avelusiva distribu	tor?	Yes	-	direct from m		sea	item/Each:	0.11	4	2.25	3.25	29.25	1
Has FDA granted waiver/exception			No	_		ce manufacturer for re	packaged product	Box/Carton/	Bundle/					
If yes, attach documentation from							, , ,	Inner Pack:						
								Case:	1.9	8.25	7.25	7.25	433.64	12
		GT	IN AND HIBCC PRODUCT	NFORMATION					1.0	0.20	1.20	7.20	100.01	
Onland to the training	_							Pallet:						
Saleable Unit of Measure x	S	aleable Quantity	HIBCC			N-14 31722032322	Unit of Use GTIN-14							
X Item/Each Box/Carton/Bundle/Inner Pack		1			003	31122032322			COST INFORMATION	N		WHO! ESAL	ER USE ONL	γ
X Case		12			203	31722032326			OCCI IIII CIMIATIC			WIIOLLOAL	LIC OOL ONL	•••
Pallet		·-			200			Regular Cos	st		Vendor #:			
								Invoice Cos		\$424.71	Whsl. Code	#:		
											Fineline Co			
								As of date:	3/15/2024					
 			Attack conv. (OAFFT)	ATA CHEET 'C'	201	ad laws DAOKAGE ""	CERT LAREL AND DUOTS OF	II.	(ACINIC DADOOD =		1			
*Please provide any additional info	ormation on noc-	2	Attach copy of SAFETY D	AIA SHEEI (SI	or non naza ردر		SERT, LABEL AND PHOTO OF signated Drop Ship Only.	PRODUCT PACK	Signature:					
r rease provide any additional into	ormation on page a	£.				See new p. 3 for De	aignated brop ailip oilly.		orginature.					



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For Designated Drop Ship Only Products, Please Use Page 3

MATE	AL HAZARD C	LASSIFICATION and TRANSPORTATION				
Is this product (check all that apply):	Ma	CDC Harved Classification				
a. Cytotoxic?	No	SDS Hazard Classification				
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	Va I	v. Ormania	Corrosive			
Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant?	No :	x Organic Inorganic	Oxidizer			
Does the product label bear a CA Prop 65 warning?	No	Steroid/Androgen	Contact Hazard			
Does the product label bear a CA Prop 65 warning?	10	Steroid/Androgen	Contact Hazard			
c. Contact Hazard?	No Do	pes the product have an Aerosol class? If yes,	No			
d. Does this product require special clean-up instructions?		entify NFPA Storage Level:	140			
(If yes, attach SDS with special instructions.)		NFPA Storage Level:				
e. Does the product contain DEHP?	No					
Is this product regulated for shipment by DOT?		the product a NICCLI begandage drugs?	No			
(if yes, answer a-e below and provide SDS)	15	the product a NIOSH hazardous drug? If yes, indicate which:	NO			
a. UN/Identification Number		ii yes, indicate which.				
b. Proper Shipping Name						
c. DOT Hazard Class		Hazai	Hazardous Waste Identification			
d. Packing Group						
e. Inhalation Hazard?	EF	PA Hazardous Waste Code:		Waste Characteristics		
Is this product regulated for shipment by IATA?	No	·				
(if yes, answer a-e below and provide SDS)		REMS or REGISTRY RESTRICTIONS				
a. UN/Identification Number						
b. Proper Shipping Name		ere a REMS on this product?	No			
c. DOT Hazard Class	lf '	Yes, is it managed with a pharmacy registry?				
d. Packing Group		Website URL:				
e. Inhalation Hazard?						
Is the product restricted for air shipment? If so, indicate restriction:		Guide Required	No			
Passenger		ed Distribution Requirement				
Cargo	Com	ments / Details: (For example, iPledge program?)				
Passenger & Cargo						
Is this a reportable quantity? No	REM		No			
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? No (if yes, identify method below)		Wholesale distributor support: Provider Name:		DEA #:		
Limited Quantity		Site Enrollment Number assigned		NCPDP#:		
Consumer Commodity, ORM-D		by Supplier:		NPI#:		
Small Quantity (49 CFR 173.4)		3 - 11 -				
Special Permit; DOT-SP		Comments				
Special Provision (listed in Column 7 of 49 CFR 172.101);						
SP#	Regi	stry:	No			
		Registry Program Contact Name:		Phone:		
ADD'L STORAGE INFORMATION		Comments				
Is the Product						
Controlled Substance? No Controlled Substance Code		RE	ETURN INSTRUCTIONS			
Controlled by State(s)? No Listed Chemical (List I or II)	No					
ARCOS Reportable? No If yes, indicate which:		act tel. # if product received damaged:	1-866-827-3647			
Schedule No. Is it a scheduled listed chemical product?:	No 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	'es	contact - customerse	rvice@camberpharma.com			
Restricted to retail pharmacy only:						
	Open	cial regulations or returns requirements for this uct in certain states?	No			
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)		which states? Other requirements? Comments?	No			
	11 50,	milen states: Other requirements: Comments:				
Comments:						
MISC	LANEOUS NO	TES and/or Image of Product Barcode:				
Pantoprazole sodium for delayed-release oral suspension should only be given by mouth mixed i	apple juice or a	pplesauce or through nasogastric (NG) tube or gastro	ostomy tube mixed in apple juice.	Do not mix pantoprazole sodium for delayed-		
release oral suspension in liquids other than apple juice or foods other than applesauce.						



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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?				