

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

						Introduction Type:	Post Launch Change		1 Final Version			Date:	3/16/	2023
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA					a. Temperature – Indicate the USP temperature range for this product.									
Application Number for NDA/A	NDA/BLA (drug); PM	IA/510(k)(med devi	ce):	21	3778			1	Temperature Range	Controlled Room -		and 25 C (68	s° – 77° F)	
Medical Device Class, if applica	able:							1						
DUNS:	82-677-4775							_	Other Temperature Range F	equirement	excursions p	ermitted to 1	5° to 30°C (59	9° to 86°F)
Proprietary Name (If Applicable)		me: Panto	prazole Sodium for Injection					I	(write in)					
Selling Unit NDC:	31722-204-10		Unit of Use NDC:				22204101		Notes					
UDI			CVX Code:			MVX Code:		1						
Description:		um for Injection 40n						I	Is this product to be shipped	to customers on ic	e?		No	
	NOTE - Product C		ution: white to off white. Pro-	duct Color after	reconstitution: c	lear colorless to light yello	DW.		Is this product to be shipped	to customers on d	ry ice?		No	
Active Ingredient(s):	Active Ingredient(s): Pantoprazole Sodium							11		_				
URL for Additional Product Information: www.camberpharma.com					b. Contact fo	or temperature excursion que	estions:	0 D-'						
Address:		www.camberpharma we (and) 800 Center			1	Address 2:		+	Name: Number:		Soma Raju 732-529-042	12		
City:	Piscataway	ive (and) 800 Center	iniai Ave, Suite i		State:	NJ Zip	: 08854	-	Group E-mail:			is ieterousa.cor	m	
Key Contact:	Customer Service				Email:	customerservice@cam		1	Group L-mail.		<u>somaraju e i</u>	ieterousa.coi	<u>11</u>	
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special reg	gulations for product in any	states?			No	
Product Therapeutic Classification	on:	Proton-Pump Inhib	itors						Special returns requirement				No	
									.,					1
	ADDITIO	ONAL PRODUCT IN	FORMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store prod	duct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship (	Only			11	Protect product (unit of sa	le) from light?			No	i
a legend device?		No	Is the Product	Unit Dose			10 Single Dose Vials	e. Shelf life:	r roteet product (dilit or sa	ic) ii oiii iigiit i			24	Months
if yes, enter class #		1.14	Orphan Drug Status			Size:	g		Initial shelf life at launch (i	f different):				Months
a product kit?		No	. •			Strength:	40mg/vial		,	•				
if yes, list NDCs of			FDA Approval Status			Strength.				ORDER INFORM	ATION			
component parts						Dosage Form:	Lyophilized Powder /							
reverse numbered?		No					Cake for Injection		Unit of Sale		What is the		unit?	
co-licensed? latex-free?		No Yes	Allergens Present				SDV Containing		Bottle  Box/Carton		1 box of 10		0 \/:ala\	
preservative-free?		Yes				Product Shape:	Lyophilized Powder /		Ampule		(vviite-iri, e.	g. 1 Box of 1	u viais)	
correctional institution block?		No					White to Off White		Glass		Minimum o	der auantity	12	Yes
opioid?		No				Product Color:	Powder (See Note Above)		Tube			uo. quu,	•	
Cannabinoid?		No	Country of Origin	India		Due deset languinte	N/A		Vial Liquid Sgl					
If Unit Dose, is item bar coded to						Product Imprint:			Vial Liquid Multi		If Yes, how		ch package	type?
hospital scanning?		No	Is this product covered u						Vial Powder Sql		1	Each		
If Unit Dose, indicate NDC here:		31722-204-31	Trade Agreements Act (	TAA)?	No				Vial Power Multi			Inner/Carton	/Pack	
								<u>J  </u>	Other: Write In			Case		
	FOR GENERIC DRUG PRODUCTS													
			FOR GENERIC DRUG FR		Δ	therized Conerio *If A	uthorized Conorio other		DU	APMACY OPDER	/ BILL LINIT			
			FOR GENERIC DRUG FR		Au		uthorized Generic, other	Dan and house		ARMACY ORDER				
I. Orange Book Rating:	AP	Dresson IV	FOR GENERIC DRUG FR		Au		uthorized Generic, other on fields are not applicable	Rec. sell unit	PH t to customer?	ARMACY ORDER	/ BILL UNIT Rx billing u		асу:	
I. Orange Book Rating: II. Generic Equivalent to What Br		Protonix® IV	FOR GENERIC DRUG FR		Au				t to customer?	ARMACY ORDER		Each	асу:	
								Rec. sell unit	t to customer?	ARMACY ORDER		Each Gram	асу:	'
			LY CHAIN SECURITY ACT						t to customer?	ARMACY ORDER		Each	асу:	
II. Generic Equivalent to What Br	and?:	DRUG SUPPI	LY CHAIN SECURITY ACT Yes						t to customer? j. 1 Vial)	ARMACY ORDER	Rx billing u	Each Gram Milliliter	acy:	
II. Generic Equivalent to What Br	and?:	DRUG SUPPI	LY CHAIN SECURITY ACT		RMATION	secti			t to customer? j. 1 Vial)		Rx billing u	Each Gram Milliliter	acy:	
II. Generic Equivalent to What Br	and?:	DRUG SUPPI	LY CHAIN SECURITY ACT Yes		RMATION	secti			t to customer? g. 1 Vial)	AND PACKING IN	Rx billing u	Each Gram Milliliter	acy:	Saleable #
II. Generic Equivalent to What Br.  Does supplier meet DSCSA defin Is product exempt from DSCSA?	and?:	DRUG SUPPI	LY CHAIN SECURITY ACT  Yes  No		RMATION GLN:	secti			t to customer? j. 1 Vial)	AND PACKING IN	Rx billing u	Each Gram Milliliter		Saleable #
II. Generic Equivalent to What Br.  Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	and?: hition of manufacture	DRUG SUPP	LY CHAIN SECURITY ACT  Yes  No		GLN: GCP: If yes, was or	secti	on fields are not applicable		t to customer? p. 1 Vial) ITEM Weight Lbs.	AND PACKING IN Dimensi Depth	Rx billing u	Each Gram Milliliter	Volume (Cube)	
Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer	and?:  ition of manufacture s exclusive distribu	DRUG SUPPI	Yes No No Yes		GLN: GCP: If yes, was or direct from m	0331722000000  riginal product purchase	on fields are not applicable	(Write-in, e.g	t to customer?  j. 1 Vial)  ITEM  Weight Lbs.  0.3	AND PACKING IN	Rx billing u  IFORMATIO  DOES (US msn  Width	Each Gram Milliliter	Volume	Pieces
II. Generic Equivalent to What Br.  Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer' Has FDA granted waiver/exceptic	and?:  iition of manufacture s exclusive distribu	DRUG SUPPI	LY CHAIN SECURITY ACT  Yes  No		GLN: GCP: If yes, was or direct from m	secti	on fields are not applicable	(Write-in, e.g	t to customer?  j. 1 Vial)  ITEM  Weight Lbs.  0.3	AND PACKING IN Dimensi Depth	Rx billing u  IFORMATIO  DOES (US msn  Width	Each Gram Milliliter	Volume (Cube)	Pieces
Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer	and?:  iition of manufacture s exclusive distribu	DRUG SUPPI	Yes No No Yes		GLN: GCP: If yes, was or direct from m	0331722000000  riginal product purchase	on fields are not applicable	(Write-in, e.g	t to customer?  g. 1 Vial)  ITEM  Weight Lbs.  0.3  Bundle/	AND PACKING IN  Dimension Depth  5.125	Rx billing u  FORMATION  Ons (US msn  Width	Each Gram Milliliter N mts.) Height 2.69	Volume (Cube) 27.5725	Pieces 1
II. Generic Equivalent to What Br.  Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer' Has FDA granted waiver/exceptic	and?:  iition of manufacture s exclusive distribu	DRUG SUPPI	Yes No  No  Yes No  No  Yes No	(DSCSA) INFO	GLN: GCP: If yes, was or direct from m	0331722000000  riginal product purchase	on fields are not applicable	(Write-in, e.g	t to customer?  j. 1 Vial)  ITEM  Weight Lbs.  0.3	AND PACKING IN Dimensi Depth	Rx billing u  IFORMATIO  DOES (US msn  Width	Each Gram Milliliter	Volume (Cube)	Pieces
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II. Generic Equivalent to What Br.  Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer! Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure	and?:  ition of manufacture s exclusive distribu- on/exemption for pro-	DRUG SUPPI er? tor? pduct?  GT aleable Quantity	Y CHAIN SECURITY ACT YES NO NO YES NO YOU NO	(DSCSA) INFO	GLN: GCP: If yes, was or direct from m Provide sour	o331722000000  riginal product purchase fir? ce manufacturer for repair.	on fields are not applicable  d  ackaged product	(Write-in, e.g	t to customer?  g. 1 Vial)  ITEM  Weight Lbs.  0.3  Bundle/	AND PACKING IN  Dimension Depth  5.125	Rx billing u  FORMATIO  ons (US msm  Width  2	Each Gram Milliliter	Volume (Cube) 27.5725	Pieces 1 20
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## **Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)**

#### Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

M.F	TERIAL 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?  Is the product a CA Prop 65 reproductive toxicant?  No  Does the product label bear a CA Prop 65 warning?  No		X Organic Inorganic Steroid/Androgen	Corrosive Oxidizer 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		Hazardous Waste Identification				
d. Packing Group e. Inhalation Hazard?	No	EPA Hazardous Waste Code:		Waste Characteristics		
Is this product regulated for shipment by IATA?	No	El A l'azardous waste dode.		Waste Offaracteristics		
(if yes, answer a-e below and provide SDS)	INU	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?)	No			
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:	No			
ADDIL OTODAGE INFORMATION		Registry Program Contact Name:		Phone:		
ADD'L STORAGE INFORMATION		Comments				
Is the Product  Controlled Substance?  Controlled Substance Code  Controlled by State(s)?  ARCOS Reportable?  Schedule No.  No  Controlled Substance Code  Listed Chemical (List I or II)  If yes, indicate which:  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	Yes	contact - customerse	rvice@camberpharma.com			
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 No	product in certain states?  If so, which states? Other requirements? Comments?	No			
Comments:						
	ISCELL ANEC	DUS NOTES and/or Image of Product Barcode:				
	IOOLLLANLU	100 NOTES and/or image of Floudet 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?