

Standard Pharmaceutical Product Information (Rx Product Only)

Common Nome					Introduction Typ	e: New Item						Date:		8/2019
Commons Names			PRODUCT INFORMATION						SPECIAL HANDL	ING AND STO	DRAGE REQ	UIREMENTS	*	
Company Name:	Camber Pharmaceuti	cals			Applic	ation: ANDA	A	a. Temperature – Indica	ate the USP tempera	ature range	for this prod	uct.		
Application Number for ND	A/ANDA/BLA (drug);	PMA/510(k)(med device)	:	202882					ure Range				en 20 and 25	C (68° – 77° I
DUNS:	82-667-4775							Other Ter	nperature Range Red	quirement				
Proprietary Name (If Applica		Name: Pantopraz	zole Sodium Delayed-Release 40n	ng 1000ct					te in)	1				1
Selling Unit NDC:	31722-713-10		Individual Unit NDC:		UPC: 3	31722713108		·						_
UDI			CVX Code:		MVX Code:			Is this pro	duct to be shipped to	customers of	n ice?		No	_
Description:	Oval shaped, bevel c	oncave punches, plain on	both sides with corresponding dye	S.				Is this pro	duct to be shipped to	customers of	on dry ice?		No	
														- '
Active Ingredient(s):		Pantoprazole Sodium						b. Contact for temperat	ure excursion ques	stions:	Soma Raju			
URL for Additional Product	Information:	www.camberpharma.com	0					Name: Number:			732-529-04	23		
Address:	1031 Centennial Ave				Address 2:			Group E-	mail·			neterousa.coi	m	
City:	Piscataway			State:	NJ Zip	08854								
Key Contact:	Customer Service			Email:	customerservice@ca	mberpharma.com		c. Special regulations f	or product in any st	tates?			No	_
Phone Number:	732-529-0430			Fax:	732-562-8788			Special re	eturns requirements f	or this produc	t?		No	_
Product Therapeutic Classif	fication:													
ADDITION	AL PROPUST INCORN	ATION	•		PRODUCT DESCRIPTI	ON INCODMATION		d. Store product (unit o					No	_
	AL PRODUCT INFORM	IATION			PRODUCT DESCRIPTI	UN INFORMATION		-	roduct (unit of sale) from light?			No	=
Is the Product								e. Shelf life:					24	Months
a legend device? reverse numbered?		No No		Size:	1000			Initial she	elf life at launch (if d	lifferent):				Months
co-licensed?		No No							C	RDER INFO	RMATION			
Is the Product		Direct-Ship Only		Strength:	40MG									
Is the Product		Unit Dose		Dosage Form	n: Tablet			Unit of Sa	ale		What is the	NDC selling	unit?	
				Dosage i om	i. Tablet				Bottle		1 box of 12			
If Unit Dose, is item bar code	ed to unit dose for hosp	ital scanning?						x	Box/Carton		(Write-in, e	.g. 1 Box of 1	0 Vials)	
If Unit Dose NDC, indicate N	IDC here:			Product Shap	pe: Oval shaped				Ampule Glass		Minimum o	rder quantity	ı?	Yes
ii onii booo nbo, inaloato n	.50 11010.			Product Colo	Yellow to Pa	o Vollow			Tube			uo. quu,		
Country of Origin		India		Froduct Colo	Tellow to Fa	e reliow			Vial Liquid Sgl					
Is this product covered unde	er the Trade Agreements	Act (TAA)?		Product Impr	rint: H126				Vial Liquid Multi		If Yes, how		ch package	type?
	-								Vial Powder Sql			Each		
												Innor/Cartor	/Dack	
									Vial Power Multi		12	Inner/Cartor Case	/Pack	
			FOR GENERIC DRUG PRODUC	TS						7	12	4	/Pack	
			FOR GENERIC DRUG PRODUC						Vial Power Multi Other: Write In]		Case	/Pack	
			FOR GENERIC DRUG PRODUC			f Authorized Generic, other	r section		Vial Power Multi Other: Write In	MACY ORDE	12 ER / BILL UNI	Case	√Pack	
I. Orange Book Rating:	AB		FOR GENERIC DRUG PRODUC			f Authorized Generic, other elds are not applicable	r section		Vial Power Multi Other: Write In PHAR	MACY ORDE	ER / BILL UNI	Case T nit to pharm		
I. Orange Book Rating:		Protonix	FOR GENERIC DRUG PRODUC				r section	Rec. sell unit to custom	Vial Power Multi Other: Write In PHAR	MACY ORDE	ER / BILL UNI	Case T nit to pharm Each		
				Auth			r section		Vial Power Multi Other: Write In PHAR	MACY ORDE	ER / BILL UNI	Case T nit to pharm Each Gram		
			FOR GENERIC DRUG PRODUC	Auth			r section	Rec. sell unit to custom	Vial Power Multi Other: Write In PHAR	MACY ORDE	ER / BILL UNI	Case T nit to pharm Each		
	at Brand?:	DRUG SUPPL	Y CHAIN SECURITY ACT (DSCS.	Auth			r section	Rec. sell unit to custom	Vial Power Multi Other: Write In PHAR]	ER / BILL UNI	T nit to pharm Each Gram Milliliter		
II. Generic Equivalent to Wh Does supplier meet DSCSA Is product exempt from DSG	at Brand?:	DRUG SUPPL	.Y CHAIN SECURITY ACT (DSCS.	Auth A) INFORMATION			r section	Rec. sell unit to custom	Vial Power Multi Other: Write In PHAR	ND PACKING	R / BILL UNI	T nit to pharm Each Gram Milliliter	acy:	
II. Generic Equivalent to Who Does supplier meet DSCSA Is product exempt from DSC If yes, select exemption:	definition of manufac	DRUG SUPPL	Y CHAIN SECURITY ACT (DSCS.	Auth A) INFORMATION			r section	Rec. sell unit to custom	Vial Power Multi Other: Write In PHAR	ND PACKING	R / BILL UNI Rx billing u INFORMATI	T nit to pharm Each Gram Milliliter ON	acy:	#Pieces:
II. Generic Equivalent to Wh Does supplier meet DSCSA Is product exempt from DS(if yes, select exemption: Other exemption - Write in	definition of manufac	DRUG SUPPL	Y CHAIN SECURITY ACT (DSCS. Yes	A) INFORMATION GLN:	fi	elds are not applicable	r section	Rec. sell unit to custom (Write-in, e.g. 1 Vial)	Vial Power Multi Other: Write In PHAR ner? ITEM AI Weight Lbs.	ND PACKING	R / BILL UNI Rx billing u INFORMATI	Tinit to pharm Each Gram Milliliter ON smts.) Width	acy:	# Pieces:
II. Generic Equivalent to Who	at Brand?: definition of manufac CSA?	DRUG SUPPL	Y CHAIN SECURITY ACT (DSCS.	A) INFORMATION GLN:		elds are not applicable	r section	Rec. sell unit to custom	Vial Power Multi Other: Write In PHAR ner? ITEM AI	ND PACKING	R / BILL UNI Rx billing u INFORMATI	T nit to pharm Each Gram Milliliter ON	acy:	# Pieces:
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II. Generic Equivalent to When the control of the c	at Brand?: definition of manufac CSA? : turer's exclusive distr	DRUG SUPPL turer?	Y CHAIN SECURITY ACT (DSCS. Yes No No No No ON ON OTIN PRODUCT INFORMATIO	Auth A) INFORMATION GLN: If Yes, was origin from mfr? If yes, attach doc	al product purchased	elds are not applicable		Rec. sell unit to custom (Write-in, e.g. 1 Vial) Item: Box/Carton/Bundle/ Inner Pack:	Vial Power Multi Other: Write In PHAR ner? ITEM Al Weight Lbs. 0.6	ND PACKING Dimer	R / BILL UNI Rx billing u INFORMATI Insions (US m Height 5	Tinit to pharm Each Gram Milliliter ON asmts.) Width	volume (Cube)	
II. Generic Equivalent to Wh Does supplier meet DSCSA Is product exempt from DSG If yes, select exemption: Other exemption - Write in Is product repackaged? Is product sold by manufact Has FDA granted waiver/exc	definition of manufac CSA? :: turer's exclusive distr ception/exemption for	ibutor?	Yes No No No No GTIN PRODUCT INFORMATIO Level Unit	Auth A) INFORMATION GLN: If Yes, was origin from mfr? If yes, attach doc Note: X 2D 2D	tal product purchased cumentation from FDA.	direct GTIN-14 003317227131	108	Rec. sell unit to custom (Write-in, e.g. 1 Vial) Item: Box/Carton/Bundle/ Inner Pack: Case: Pallet: UPC:	Vial Power Multi Other: Write In PHAR PHAR Weight Lbs. 0.6 8.15 Case:	ND PACKING Dimer	R / BILL UNI Rx billing u INFORMATI Insions (US m Height 5	Tinit to pharm Each Gram Milliliter ON asmts.) Width	volume (Cube)	12
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II. Generic Equivalent to When the control of the c	at Brand?: definition of manufac CSA? : : turer's exclusive distr ception/exemption for	ibutor? product?	Y CHAIN SECURITY ACT (DSCS.	Auth A) INFORMATION GLN: If Yes, was origin from mfr? If yes, attach doc N Ide X ZD ZD ZD ZD ZD ZD ZD ZD	al product purchased cumentation from FDA. Linear	direct GTIN-14 003317227131	108	Rec. sell unit to custors (Write-in, e.g. 1 Vial) Item: Box/Carton/Bundle/ Inner Pack: Case: Pallet: UPC:	Vial Power Multi Other: Write In PHAR PHAR Weight Lbs. 0.6 8.15 Case: Carton: NFORMATION	ND PACKING Dimer	RX billing u RX billing u BINFORMATI SINFORMATI SINFORMATI SINFORMATI SINFORMATI Vendor #:	Case Tinit to pharm Each Gram Milliliter ON width 3 9.5	Volume (Cube)	12 1080
II. Generic Equivalent to When the control of the c	at Brand?: definition of manufac CSA? : : turer's exclusive distr ception/exemption for	ibutor? product?	Y CHAIN SECURITY ACT (DSCS.	Al INFORMATION GLN: If Yes, was origin from mfr? If yes, attach doc N N N N N N D D D D D D D D D D D D D	al product purchased cumentation from FDA. Linear	direct GTIN-14 003317227131	108	Rec. sell unit to custom (Write-in, e.g. 1 Vial) Item: Box/Carton/Bundle/ Inner Pack: Case: Pallet: UPC: COST Regular Cost Invoice Cost (WAC) (\$) Federal Excise Tax Per	Vial Power Multi Other: Write In PHAR PHAR Weight Lbs. 0.6 8.15 Case: Carton: INFORMATION	Dimer Depth	RX billing u RX billing u BINFORMATI SINFORMATI SINFORMATI SINFORMATI SINFORMATI Vendor #:	Case Tinit to pharm Each Gram Milliter ON Insmts.) Width 3 9.5	Volume (Cube)	12 1080
II. Generic Equivalent to When the control of the c	at Brand?: definition of manufac CSA? : : turer's exclusive distr ception/exemption for	ibutor? product?	Y CHAIN SECURITY ACT (DSCS.	Al INFORMATION GLN: If Yes, was origin from mfr? If yes, attach doc N N N N N N D D D D D D D D D D D D D	al product purchased cumentation from FDA. Linear	direct GTIN-14 003317227131	108	Rec. sell unit to custom (Write-in, e.g. 1 Vial) litem: Box/Carton/Bundle/ Inner Pack: Case: Pallet: UPC: COST Regular Cost Invoice Cost (WAC) (\$)	Vial Power Multi Other: Write In PHAR PHAR Weight Lbs. 0.6 8.15 Case: Carton: INFORMATION	Dimer Depth	RX billing u RX billing u EINFORMATI RISIONS (US m Height 5 6 Vendor #: Whst. Code	Case Tinit to pharm Each Gram Milliter ON Insmts.) Width 3 9.5	Volume (Cube)	12 1080
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Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL H	HAZARD CLASSIFICATION and TRANSPORTATION	
Is this product (check all that apply):		
a. Cytotoxic?	SDS Hazard Classification	
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	ODO HAZARA CIASSINISARON	
Is the product a CA Prop 65 carcinogen?	Organic Corrosive	
Is the product a CA Prop 65 carcinogen?	Inorganic Oxidizer	
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard	
a Contact Hamard?	Assess Class Identify NEDA Ctaypes Lavely	
c. Contact Hazard?	Aerosol Class; Identify NFPA Storage Level:	
d. Does this product require special clean-up instructions? No	L d L L L NICOLL L L L C	
(If yes, attach SDS with special instructions.)	Is the product a NIOSH hazardous drug?	
e. Does the product contain DEHP?	If yes, indicate which:	
Is this product regulated for shipment by DOT or IATA? No		
(if yes, answer a-e below and provide SDS)		
a. UN/Identification Number		
b. Proper Shipping Name	Hazardous Waste Identification	
c. DOT Hazard Class	EPA Hazardous Waste Code:	
d. Packing Group	·	
e. Inhalation Hazard?		
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS	
Passenger	Is there a REMS on this product?	
Cargo	If Yes, is it managed with a pharmacy registry?	
Passenger & Cargo	Website URL:	
<u> </u>	website ort.	
Is this a reportable quantity? No		
RQ Threshold:	Comments / Details: (For example, iPledge program?)	
Is this a marine pollutant? No		
Is this product shipped utilizing an authorized DOT exception or Special Permit?		
No (if yes, identify method below)	REMS: No	
Limited Quantity	REMS Program Manager Name: Phone:	
Consumer Commodity, ORM-D	Supplier Manages REMS registry exclusively: No No	
Small Quantity (49 CFR 173.4)	Wholesale distributor support: No No	
Special Permit; DOT-SP	Provider Name:	
Special Provision (listed in Column 7 of 49 CFR 172.101);	Site Enrollment Number assigned DEA #: No	
SP#	by Supplier: PCPDP #: No	
	NPI#: No	
ADD'L STORAGE INFORMATION		
Is the Product	Comments	
Controlled Substance? No		
Controlled by State(s)?	Registry: No	
ARCOS Reportable? No	Registry Program Contact Name: Phone:	
Schedule No. (inc. N for non-narcotic)	Comments	
Controlled Substance Code		
Listed Chemical (List I or II) No	RETURN INSTRUCTIONS	
If yes, indicate which:		
Is it a scheduled listed chemical product?: No	Contact tel. # if product received damaged: 732-529-0430	
CLASS OF TRADE RESTRICTION:	ls product returnable for credit:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No	URL/Link to returns policy: contact - customerservice@camberpharma.com	
Restricted to retail pharmacy only: Yes	Special regulations or returns requirements for this product in certain states? No	
Restricted to hospital, clinics, and physician offices only: No	If so, which states? Other requirements? Comments?	
Restricted from US territories? (explain in comments) No	Total Miles Carlo Capacita Carlo Capacita Capaci	
Comments:		
MISCELLAN	NEOUS NOTES and/or Image of Product Barcode:	



Standard Pharmaceutical Product Information (Page 3)

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: Case pack Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone: Yes Fax Number: 732-562-8788 No Phone No.: No Site Address: 732-529-0430 x466 x465 x467 x470 Name: Phone:	Shipping lead time of PO: Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:	Eastern Days No No Yes
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Process	
Expedited freight fees billed with each order: No	Overnight receipt available:	Yes
Drop Ship service fee billed with each order: No		Eastern
Drop Ship miscellaneous fees billed: Comments:		x Monday x Tuesday x Wednesday x Thursday Friday
	Priority Overnight receipt available:	Yes
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) No Comments:	EDI: Yes Overnight Fees apply: Yes Other fees apply: No	2:30PM EST No 732-562-8788
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 s If so, which states? Other requirements? Comments?	732-529-0430 Yes states? Yes
	ADDITIONAL INFORMATION	
	Is product order for scheduled patient procedure? Is product order for restocking purposes?	No No