

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014							Intro	duction Ty	pe:	Post Laund	ch Change		Final Version			Date:	4/27	/2017
				PRODUCT INFORM	IATION								SPECIAL HANDL	ING AND ST	ORAGE REQ	UIREMENTS	*	
	Camber Pharmaceut							Applic	cation:	ļ	ANDA	a. Temperature – India		ature range				
Application Number for NDA	A/ANDA/BLA (drug);	PMA/510(k)(med	d device):		20	02843						Tempera	ature Range		Controlled R	oom – betwe	en 20 and 25	C (68° – 77° I
	82-667-4775											Other Te	emperature Range Re	quirement				
Proprietary Name (If Applicable) and Established Name: Pantoprazole Sodium Delayed-Release Tablets 40MG 90CT							(write in)											
	31722-713-90			Individual Unit NDC	:	31722-713-90			331722713	3900								
UDI	NA			CVX Code:			MVX	Code:	NA			Is this pr	roduct to be shipped to	o customers o	on ice?		No	-
Description: White to off-white, round, embossed with '126' on upper and 'H' on lower							Is this product to be shipped to customers on dry ice? <u>No</u>											
Active Ingredient(s):		Pantoprazole S	odium									b. Contact for tempera Name:	ature excursion que	stions:	Soma Raju			
URL for Additional Product In	JRL for Additional Product Information: www.camberpharma.com							Number	r:		732-529-0423							
Address:	1031 Centennial Avenue				Address 2:				Group E	E-mail:		somaraju@h	eterousa.coi	n				
City:	Piscataway				State: NJ Zip: 08854													
Key Contact:	Customer Service				Email: customerservice@camberpharma.com				c. Special regulations					No	_			
Phone Number:	732-529-0430				Fax: 732-562-8788				Special	returns requirements t	for this produc	Ct /		No	-			
Product Therapeutic Classification:																		
d. ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION								d. Store product (unit of sale) upright? No Protect product (unit of sale) from light? No										
Is the Product												e. Shelf life:	product (and or out	,,			24	Months
a legend device?			No				Г						helf life at launch (if o	lifferent).			24	Months
reverse numbered?			No			Size:	!	90				initial SI						
co-licensed?	No						ORDER INFORMATION											
Is the Product		Direct-Ship Onl	у			Strength:		40 Mg										
Is the Product		Unit of Use				Dosage Form		Oral solid ta	blet			Unit of S				NDC selling	unit?	
						•	L					x	Bottle Box/Carton		1 box of 24	bottles .g. 1 Box of 1	0.)((ala)	
If Unit Dose, is item bar code	d to unit dose for hos	pital scanning?					Г					x	Ampule		(write-in, e	.g. i box oi i	u viais)	
If Unit Dose NDC, indicate ND	DC here:					Product Shap	e:	round					Glass		Minimum o	rder quantity	1?	Yes
						Product Color	. 1	white to off-	white				Tube			,		
Country of Origin		India				FIGULET COID		white to on-	white				Vial Liquid Sgl					
Is this product covered under the Trade Agreements Act (TAA)?									Vial Liquid Multi		If Yes, how		ch package	type?				
		-	No				L					Vial Powder Sql Each Vial Power Multi Inner/Carton/Pack						
					L								Other: Write In		24	Case	FACK	
-				FOR GENERIC DRUG P	PRODUCTS											ouoo		
Authorized Generic * If Authorized Generic, other section																		
	AB	_						1	neius are n	ot applicable		Rec. sell unit to customer? Rx billing unit to pharmacy:						
II. Generic Equivalent to What Brand?: Protonix												Each						
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION								(Write-in, e.g. 1 Vial)				Gram Milliliter						
					()											INTIMACOT		
Does supplier meet DSCSA o		cturer?		Yes	G	LN:						ITEM AND PACKING INFORMATION						
Is product exempt from DSC	SA?		N	ło	_													
If yes, select exemption: Other exemption - Write in:										-			Weight Lbs.	Dime	nsions (US m Height	width	Volume (Cube)	# Pieces:
Is product repackaged?			N	lo	lf	Yes, was origina	al product	nurchased	direct	_		Item:		Depth			(Cube)	
Is product sold by manufactu	urer's exclusive dist	ributor?		No		om mfr?							0.1		3	1.5		
Has FDA granted waiver/exce				No	lf	yes, attach doc	umentatio	n from FDA	۱.			Box/Carton/Bundle/						
												Inner Pack:						
				GTIN PRODUCT INFO								Case:	3.05	10	4.5	7	0.182	24
				Level	Saleable Unit			(Quantity	GTIN-14		Pallet:						
Serialized?	Yes	ſ	X I	Item		X 2D		Linear	1	00331722	713900							4416
If not, when?				Box/Carton/Bundle/Inner Pack	k	2D		Linear				UPC:	Case:					
Items aggregated?	Yes	_		Case	x	X 2D		Linear	24	20331722	2713904		Carton:					
Pallet 2D Linear Linear							COST INFORMATION WHOLESALER USE ONLY:											
		ļ			+	2D 2D	\vdash	Linear Linear				COST	INFORMATION			WHOLESAL	LER USE ON	LY:
		ŀ	——		+	2D 2D	\vdash	Linear Linear				Regular Cost			Vendor #:			
												Whsi. Code #:						
							Federal Excise Tax Pe		<i></i>	Fineline Co								
												As of date:						
				Attach copy of SAFETY	DATA SHEET	(SDS) or non has						DUCT PACKAGING and B/						
*Please provide any addition	al information on pa	ige 2.					See new	p. 3 for De	esignated	Drop Ship O	Only.	Signatu	ire:					



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

le this product (check all that apply)								
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? No	Organic							
Is the product a CA Prop 65 reproductive toxicant?	Inorganic Oxidizer							
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard							
c. Contact Hazard? No	Aerosol Class; Identify NFPA Storage Level:							
d. Does this product require special clean-up instructions? No								
(If yes, attach SDS with special instructions.)	Is the product a NIOSH hazardous drug?							
e. Does the product contain DEHP? No	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: NA							
d. Packing Group								
e. Inhalation Hazard?								
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? Yes							
Passenger								
Cargo	If Yes, is it managed with a pharmacy registry? No							
Passenger & Cargo	Website URL: N/A							
Is this a reportable quantity? No								
RQ Threshold:	Comments / Details: (For example, iPledge program?)							
Is this a marine pollutant? No	None							
Is this product shipped utilizing an authorized DOT exception or Special Permit?								
No (if yes, identify method below)	REMS: Yes							
Limited Quantity	REMS Program Manager Name: Phone:							
Consumer Commodity, ORM-D	Supplier Manages REMS registry exclusively: No							
Small Quantity (49 CFR 173.4)	Wholesale distributor support: 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 None							
Controlled Substance? No								
Controlled by State(s)? No	- Registry: No							
ARCOS Reportable? No	Registry Program Contact Name: Phone:							
Schedule No. (inc. N for non-narcotic)	Comments							
Controlled Substance Code	1							
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:	Is product returnable for credit: Yes							
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								
Comments:								
comments:								
MISCELL	ANEOUS NOTES and/or Image of Product Barcode:							
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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: Autofax Yes b. Autofax No Fax Number: c. Fax Yes Fax Number: d. Phone only No Phone No.: e. Supplier Web Site only No Site Address: Minimum Order Quantity: case pack 732-529-0430 x466 x465 x467 x470 Contracted 3PL company / contact #: Name: Phone:	Purchase order daily receipt cut off time by supplier Cut off time: 2:30PM Eastern Shipping lead time of PO: 24/48 Hours Days Ships same day for next day receipt: No No Ships for second day receipt: No No Ships regular ground for 3-10 days receipt: Yes						
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing						
Expedited freight fees billed with each order: No Drop Ship service fee billed with each order: No Drop Ship miscellaneous fees billed: No Comments: Image: No Comments: Image: No Class of Trade Restriction: No Restricted to retail pharmacy, hospitals, clinics and physician offices No Yes Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No	Overnight receipt available: Yes PO Receipt cut off time: 2:30PM Eastern Days of week overnight is available: X Monday X Tuesday Wednesday X Thursday Friday Priority Overnight receipt available: Yes PO Receipt Cut off time: 2:30PM EST Saturday Overnight receipt available: No PO Receipt Cut off time: No Order receipt method: Phone: No Fax: Yes Fax #:						
Comments:	rax. res rax #. res EDI: Yes Overnight Fees apply: Yes Other fees apply: No						
Other Data Information Required to Process PO:	Return Instructions						
Patient Procedure Date:	Contact # if product is received damaged: 732-529-0430 Is product returnable for credit: Yes URL/Link to returns policy:						
	ADDITIONAL INFORMATION						