

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014 Introduction Type: New Item										Final Version			Date:			
PRODUCT INFORMATION									SPECIAL HANDLING AND STORAGE REQUIREMENTS*							
Company Name:	Camber Pharmaceuticals Application: ANDA								a. Temperature – Indicate the USP temperature range for this product.							
Application Number for ND	DA/ANDA/BLA (drug); PMA/510(k)(med device):			203083	203083				Temperature Range Controlled Room – between 20 and 25 C (68° – 77° f							
DUNS:	826774775									Other Te	quirement					
Proprietary Name (If Application	ble) and Established	ICT						te in)								
Selling Unit NDC:	31722-571-30 Individual Unit NDC:					UPC: 331722571302										•'
UDI	CVX Code:				MVX Code:					Is this product to be shipped to customers on ice? No						
Description: Capsule, Opaque, pink and black, 'H' on cap and '167' on body										Is this product to be shipped to customers on dry ice? No						
Active Ingredient(s): Lansoprazole									b. Contact for temperature excursion questions:							
UDI for Additional Product Information									Name:		Soma Raju 732-529-0423					
URL for Additional Product Information: www.camberpharma.com Address: 1031 Centennial Avenue				Address 2:					Number: Group E		rsz-szy-u4zs somaraju@heterousa.com					
City:	Piscataway				State: NJ Zip: 08854			- Group E	-man.		Somarajuwi	ieterousa.co				
Key Contact:	Customer Service				Email: customerservice@camberpharma.com				c. Special regulations f	or product in any st	tates?			No		
Phone Number:	732-529-0430				Fax: 732-562-8788					Special returns requirements for this product? No						
Product Therapeutic Classifi	cation:															
				•						d. Store product (unit of	f sale) upright?				No	
ADDITIONA	L PRODUCT INFORM	IATION			PI	RODUCT DES	SCRIPTION IN	IFORMA	TION	Protect	product (unit of sale) from light?			No	
Is the Product										e. Shelf life: 24 Moi					Months	
a legend device?	ice? No			Siz	Size: 30					Initial sh	elf life at launch (if	different):				Months
reverse numbered?	No				00											
co-licensed?		No Direct-Ship Only	<u> </u>	Str	ength:	30				ORDER INFORMATION						
Is the Product Is the Product		Neither	-1							Unit of S	alo		What is the	NDC selling	unit?	
li dino i roddonii			—	Dos	sage Form:	Oral	Solid - DR Ca	psule			Bottle		1 bottle of 3			
If Unit Dose, is item bar code	al én conié along fou bono	Cunimana lati.									Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	<u> </u>
		No No	1	Pro	Product Shape: Capsule						Ampule					
If Unit Dose NDC, indicate Ni	DC here:				Capsule					Glass Minimum order quantity? Yes					Yes	
Country of Origin		la dia		Pro	Product Color: Opaque, pink and black					Tube						
Country of Origin India									Vial Liquid Sgl Vial Liquid Multi If Yes, how many of which package type?							
Is this product covered under the Trade Agreements Act (TAA)?				Pro	Product Imprint: 'H' on cap and '167' on body.					Vial Powder Sql 24 Each					ype.	
<u></u>								Vial Power Multi Inner/Carton/Pack								
											Other: Write In	_		Case		
FOR GENERIC DRUG PRODUCTS																
				_	Autho	rized Conorio	*If Auth	orizod C	anorio other coetien		DHAD	MACY ORDE	P/RIII IIN	т		
1.0 7.17.					Authorized Generic *If Authorized Generic, other section fields are not applicable					Rec. sell unit to customer?			Rx billing unit to pharmacy:			
I. Orange Book Rating: AB II. Generic Equivalent to What Brand?: Prevacid									Rec. sell utilit to custon	iei r	1	KX billing u	Each	acy:		
The second Equitation to Make State of the second s										(Write-in, e.g. 1 Vial)		_		Gram		
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION												Milliliter				
Does supplier meet DSCSA		turer?	Yes No	GLN:		0331722000	000				ITEM AN	ND PACKING	INFORMAT	ION		
Is product exempt from DSC If yes, select exemption:	SAY		140									Dimen	nsions (US m	iemte \	Volume	
Other exemption - Write in:											Weight Lbs.	Depth	Height	Width	(Cube)	# Pieces:
Is product repackaged?		<u>L</u>	No	If Yes,	was origina	al product pu	rchased direc	:t		Item:	0.1		3	1.5	()	1
Is product sold by manufactu	urer's exclusive distri	butor?		from m	nfr?			_			0.1		3	1.5		
Has FDA granted waiver/exc	eption/exemption for	product?	No	If yes,	attach docu	umentation fro	om FDA.			Box/Carton/Bundle/						
			OTIN PROPILOT INCORM	ATION						Inner Pack:						
			GTIN PRODUCT INFORM	Saleabl						Case:	2.4	10	4.5	6.5		24
			Level	e Unit			Quantit	hy GT	ΓIN-14	Pallet:						
Serialized?	Yes	х			X 2D	Linea			331722571302	III unct.						
If not, when?		1	Box/Carton/Bundle/Inner Pack		2D	Linea	ar			UPC:	Case:			l l		
Items aggregated?	Yes	Х	Case		X 2D	Linea	ar 24	30	331722571303		Carton:					
	Pallet 2D Linear 2D Linear						COST INFORMATION WHOLESALER USE ONLY:									
					2D 2D	Linea				COST	NFORMATION			WHOLESAL	ER USE ONL	.т:
					2D 2D	Linea		+ -		Regular Cost			Vendor #:			
		 			2D	Linea		1		Invoice Cost (WAC) (\$)		\$10,00	Whsl. Code	#:		
		<u> </u>		1			<u> </u>			Federal Excise Tax Per	Unit of Sale	Ţ.I.00	Fineline Co			
										As of date:]			
1		10.2	Attach copy of SAFETY DATA	SHEET (SDS)	or non haza		KAGE INSERT			ODUCT PACKAGING and E	ARCODE.					



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): a. Cytotoxic? SDS Hazard Classification No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? Oxidizer No Inorganic Does the product label bear a CA Prop 65 warning? No Steroid/Androgen Contact Hazard c Contact Hazard? Nο 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 Hazardous Waste Identification b. Proper Shipping Name c. DOT Hazard Class EPA Hazardous Waste Code: d. Packing Group e. Inhalation Hazard? No REMS or REGISTRY RESTRICTIONS Is the product restricted for air shipment? If so, indicate restriction: Passenger Is there a REMS on this product? No Cargo If Yes, is it managed with a pharmacy registry? Passenger & Cargo Website URL: Is this a reportable quantity? 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? (if yes, identify method below) REMS: Limited Quantity REMS Program Manager Name: Phone: Consumer Commodity, ORM-D Supplier Manages REMS registry exclusively: Small Quantity (49 CFR 173.4) Wholesale distributor support: Special Permit: DOT-SP Provider Name: Special Provision (listed in Column 7 of 49 CFR 172.101); Site Enrollment Number assigned DEA #: by Supplier: PCPDP #: NPI#: ADD'L STORAGE INFORMATION Is the Product... Comments Controlled Substance? No Controlled by State(s)? No Registry: ARCOS Reportable? No Registry Program Contact Name: Schedule No. (inc. N for non-narcotic) Comments Controlled Substance Code Listed Chemical (List I or II) No RETURN INSTRUCTIONS If yes, indicate which: 732-529-0430 Is it a scheduled listed chemical product?: No Contact tel. # if product received damaged: **CLASS OF TRADE RESTRICTION:** Is product returnable for credit: contact - customerservice@camberpharma.com No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes URL/Link to returns policy: No Restricted to retail pharmacy only: No Special regulations or returns requirements for this product in certain states? 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: MISCELLANEOUS 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	Purchase order daily receipt cut off time by supplier Cut off time: Eastern
b. Autofax c. Fax d. Phone only Fax Number: Phone No.:	Shipping lead time of PO: Hours Days
e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	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 Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:	Overnight receipt available:
Drop Ship service fee billed with each order:	PO Receipt cut off time: Eastern
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, clinics and physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # 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?