

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014						Introducti	on Type:	New Item		Final Version			Date:	5/7/	/2019
			PRODUCT INFORM	ATION						SPECIAL HANDL	ING AND ST	ORAGE REQ	UIREMENTS	*	
Company Name:	Camber Pharmaceuti	cals					Application:		a. Temperature – Indi	cate the USP temper	ature range	for this prod	uct.		
Application Number for ND):			ı				ature Range				en 20 and 25	5 C (68° – 77° I
DUNS:				<u>. </u>					Other Te	emperature Range Re	quirement				
Proprietary Name (If Applica	ble) and Established	Name: Glycerin I	Liquid						 1	rite in)	quironioni				1
Selling Unit NDC:	31722-939-47	•	Individual Unit NDC:	:		UP	C: 331722	93947	<u> </u>	,			•	•	_
UDI		•	CVX Code:			MVX Code	::		Is this p	roduct to be shipped to	customers of	on ice?		No	_
Description:	Liquid								Is this p	roduct to be shipped to	customers of	on dry ice?		No	
												•			-
Active Ingredient(s):									b. Contact for temper	ature excursion que	stions:				
									Name:			Soma Raju	00		
URL for Additional Product I Address:	1031 Centennial Ave	www.camberpharma.com	1	1		Address 2:			Number			732-529-04	heterousa.cor		
City:	Piscataway	nue			State:	NJ	Zip:	08854	Group I	-maii:		Suriarajuer	leterousa.com	11	
Key Contact:	Customer Service				Email: customerservice@camberpharma.com			c. Special regulations	for product in any s	tates?			No		
Phone Number:	732-529-0430				Fax: 732-562-8788			Special returns requirements for this product? No			_				
Product Therapeutic Classif	ication:								_						-
									d. Store product (unit	of sale) upright?				No	
ADDITION	AL PRODUCT INFORM	IATION			P	RODUCT DESC	CRIPTION IN	FORMATION	Protect	product (unit of sale) from light?	•		No	_
Is the Product			ĺ						e. Shelf life:					24	Months
a legend device?		No	ĺ		Size:	473ml			Initial sl	nelf life at launch (if o	different):				Months
reverse numbered?		No	ĺ		0.20.		'								
co-licensed?		No Direct-Ship Only	ĺ		Strength:					C	ORDER INFO	RMATION			
Is the Product Is the Product		Unit of Use	ĺ						Unit of	Sale		What is the	NDC selling	unit?	
is the roudet		Grant Gr GGG	ĺ		Dosage Form:	Liquid			X X	Bottle		1 case of 6		unit.	
If Unit Dose, is item bar code		ital accession()	ĺ						"	Box/Carton			.g. 1 Box of 1	0 Vials)	
II Onit Dose, is item bar code	ed to unit dose for nosp	ital scanning?	ĺ		Product Shape	e: liquid				Ampule					
If Unit Dose NDC, indicate N	DC here:		ĺ		outure on ape					Glass		Minimum o	rder quantity	/?	Yes
0		USA	ĺ		Product Color:	Clear				Tube					
Country of Origin			ĺ						Vial Liquid Sgl Vial Liquid Multi If Yes, how many of which package type?						
Is this product covered under	r the Trade Agreements	Act (TAA)?	ĺ		Product Imprin	nt: N/A				Vial Powder Sql		11 103, 1104	Each	on package	турс.
			ĺ						'	Vial Power Multi			Inner/Carton	√Pack	
										Other: Write In	_	1	Case		
			FOR GENERIC DRUG P	RODUCTS											
				г			*16 * 41			DHAD	MACY ORDE	ER / BILL UNI	IT.		
	Lin				Autno	rized Generic		orized Generic, other section re not applicable			IWACTORD				
I. Orange Book Rating:	NR						noido di	то постаррявально	Rec. sell unit to customer?			Rx billing unit to pharmacy:			
II. Generic Equivalent to What Brand?:				(Write-in, e.g. 1 Vial) x Each Gram											
		DRUG SUPPL	LY CHAIN SECURITY ACT	(DSCSA) INFO	DRMATION				(vviite iii, e.g. i viai)			х	Milliliter		
													-		
Does supplier meet DSCSA			Yes	GLN	1 :					ITEM A	ND PACKING	INFORMATI	ON		
Is product exempt from DSC	CSA?		No	_							Dime	: (UC		Volume	
If yes, select exemption: Other exemption - Write in:										Weight Lbs.	Depth	nsions (US m Height	Width	(Cube)	# Pieces:
Is product repackaged?	•		No	If Ye	es. was origina	I product purch	nased direct		Item:		Deptiii			(0000)	
Is product sold by manufact	turer's exclusive distr		No		n mfr?				• '	1.4		7.5	2.5		
Has FDA granted waiver/exc	eption/exemption for	product?	No	If ye	s, attach docu	mentation fron	n FDA.		Box/Carton/Bundle/						
									Inner Pack:						
			GTIN PRODUCT INFOR						Case:	8.9	8	8.5	6.5	2.55	6
			Level	Saleable Unit			Quantit	y GTIN-14	Pallet:						+
Serialized?			Item		2D	Linear	Quaritit	1)						2004
If not, when?			Box/Carton/Bundle/Inner Pack	k	2D	Linear			UPC:	Case:		<u> </u>			
Items aggregated?			Case		2D	Linear				Carton:					
			Pallet		2D	Linear									
				\vdash	2D	Linear			Cos	INFORMATION			WHOLESAL	LER USE ON	LY:
					2D 2D	Linear			Regular Cost			Vendor #:			
		\vdash		+-	2D 2D	Linear			Invoice Cost (WAC) (S	5)	\$20.62		a #:		
									Federal Excise Tax Pe		Ψ20.02	Fineline Co			
									As of date:						
										-					
			Attach copy of SAFETY [DATA SHEET (S	SDS) or non haz			Γ, LABEL AND PHOTO OF PR	ODUCT PACKAGING and B.	ARCODE.					
*Please provide any addition	nal information on page	ge 2.				See new p. 3	for Designat	ed Drop Ship Only.	Signatu	re:					



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? No	SDS 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? Does the product label bear a CA Prop 65 warning?	Organic Corrosive Inorganic Oxidizer Steroid/Androgen 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 Is this product regulated for shipment by DOT or IATA? No	Aerosol Class; Identify NFPA Storage Level: Is the product a NIOSH hazardous drug? If yes, indicate which:						
(if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification EPA Hazardous Waste Code:						
e. Inhalation Hazard? Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:						
Is this a reportable quantity? No RQ Threshold: Is this a marine pollutant? Is this product shipped utilizing an authorized DOT exception or Special Permit? No (if yes, identify method below)	Comments / Details: (For example, iPledge program?) REMS:						
Limited Quantity Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4) Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: No Provider Name: Site Enrollment Number assigned by Supplier:	DEA #: No PCPDP #: No NPI #: No					
ADD'L STORAGE INFORMATION		N11π					
Is the Product Controlled Substance? No	Registry: Registry Program Contact Name: Comments	Phone:					
Listed Chemical (List I or II) No	RETURN INSTRUCTIONS						
If yes, indicate which: Is it a scheduled listed chemical product?: CLASS OF TRADE RESTRICTION:	Contact tel. # if product received damaged: 732-529-0430 Is product returnable for credit: 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: No Restricted from US territories? (explain in comments) No	URL/Link to returns policy: contact - customerservice@camberpharma.com Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments?						
Comments:	WEALS NOTES and as lower of Product Personal						
MISCELLA	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 Yes No Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time: 2:30PM Eastern					
c. Fax Yes Fax Number: 732-562-8788 d. Phone only No Phone No.:	Shipping lead time of PO: 24/48 Hours Days					
e. Supplier Web Site only No Site Address:	Ships same day for next day receipt: No No					
Minimum Order Quantity: case pack	Ships for second day receipt: No					
Supplier's Customer Service Number: 732-529-0430 x466 x465 x467 x470	Ships regular ground for 3-10 days receipt: Yes					
Contracted 3PL company / contact #: Name: Phone:						
	0					
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing					
Expedited freight fees billed with each order: No	Overnight receipt available: Yes					
Drop Ship service fee billed with each order: No No	PO Receipt cut off time: 2:30PM Eastern					
Drop Ship miscellaneous fees billed: No	Days of week overnight is available:					
Comments:	x Tuesday x Wednesday Thursday x Friday					
	Priority Overnight receipt available: Yes					
Class of Trade Restriction:	PO Receipt Cut off time: 2:30PM EST					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	Saturday Overnight receipt available: No					
Restricted to retail pharmacy only: Yes	PO Receipt Cut off time:					
Restricted to hospital, clinics, and physician offices only: No	Order receipt method: Phone: Yes Phone #:					
Restricted from US territories? (explain in comments) No	Fax: Yes Fax #: 732-562-8788					
Comments:	EDI: Yes					
	Overnight Fees apply: Other fees apply: No					
Other Data Information Required to Process PO:	Return Instructions					
·						
Patient Procedure Date: Physician Name:	Contact # if product is received damaged: 732-529-0430 Is product returnable for credit: Yes					
Physician/Clinic Phone #	URL/Link to returns policy:					
Physician State License #	Special regulations or returns requirements for this product in certain states? Yes					
Physician/Clinic DEA #:	If so, which states? Other requirements? Comments?					
Physician/Clinic Specialty:						
Miscellaneous Notes:						
	ADDITIONAL INFORMATION					
	Is product order for scheduled patient procedure?					