

## **Standard Pharmaceutical Product Information (Rx Product Only)**

© August 2014 Introduction Type: New Item									ı		Final Version			Date:	5/1/	2018	
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			):	21	0175							ture Range	•			een 20 and 25	C (68° – 77°
DUNS:	82-667-4775										Other Te	mperature Range Red	guirement				
Proprietary Name (If Applical	ame (If Applicable) and Established Name: Oxymorphone Hydrochloride 10mg 100ct										ite in)					1	
Selling Unit NDC:	31722-930-01		Individual Unit NDC:					3317229300	17								_
UDI CVX Code:					MVX	Code:				Is this pr	oduct to be shipped to	customers of	on ice?		No	_	
Description: Pink round flat tablets de-bossed with 'T278' on one side and 'Plain' on the other side.											Is this pr	oduct to be shipped to	customers of	on dry ice?		No	_
Action beautifully)										b. Contact for temperature excursion questions:							
Active Ingredient(s): Oxymorphone Hydrochloride										Name:	Soma Raju						
URL for Additional Product Information: www.camberpharma.com									Number:			732-529-0423					
Address:	1031 Centennial Avenue				Address 2:					Group E	somaraju@heterousa.com						
City:	Piscataway				State:	NJ		Zip: 08854									
Key Contact: Phone Number:	Customer Service 732-529-0430				Fax: customerservice@camberpharma.com 732-562-8788						c. Special regulations for product in any states?  Special returns requirements for this product?				No No		
Product Therapeutic Classifi					Fdx. //32-302-0/00					Special returns requirements for this product?						-	
1 Todact Therapeatic Glassin	iodilon.				_						d. Store product (unit	of sale) upright?				No	
ADDITIONA	AL PRODUCT INFORM	ATION			F	PRODUCT	DESCRIPT	TION INFORT	MATION		Protect product (unit of sale) from light?						
Is the Product															Months		
a legend device?		No				Size: 100CT										Months	
reverse numbered?	No				Size.			10001			ORDER INFORMATION						
co-licensed? Is the Product					Strength:		10MG					Ü	KDEK INFOR	KMATION			
Is the Product	Direct-Ship Only Unit Dose									Unit of S	Sale		What is the	NDC selling	unit?		
					Dosage Form:	:	Tablet					Bottle		1 box of 24			
If Unit Dose, is item bar coded to unit dose for hospital scanning?											х	Box/Carton		(Write-in, e	.g. 1 Box of 1	0 Vials)	
		, , , , , , , , , , , , , , , , , , ,			Product Shape: Round					Ampule Glass Minimum order quantity? Yes					Yes		
If Unit Dose NDC, indicate NDC here:										Glass Tube		wiinimum o	rder quantity	18	res		
Country of Origin		USA			Product Color: Pink					Vial Liquid Sgl							
Is this product covered under the Trade Agreements Act (TAA)?					Product Imprint: T278'				Vial Liquid Multi If Yes, how many of which package type?						type?		
lo uno producti coronad undo uno riduco rigi comonio rici (1747).									· · · · · · · · · · · · · · · · · · ·				Each Inner/Cartor	/Deel			
												Other: Write In		24	Case	Pack	
FOR GENERIC DRUG PRODUCTS																	
															_		
1			-	Authorized Generic *If Authorized Generic, other section fields are not applicable				r section	PHARMACY ORDI								
I. Orange Book Rating: AB II. Generic Equivalent to What Brand?: Opana				notes are not applicable					Rec. sell unit to customer?			Rx billing unit to pharmacy:  Each					
opana										(Write-in, e.g. 1 Vial)		J		Gram			
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION										( ,				Milliliter			
		_	V									ITEM 44	ID DAOKING	INFORMAT	101		
Is product exempt from DSCSA of	s supplier meet DSCSA definition of manufacturer?  Yes  No  No										HEMAN	ID PACKING	INFORMAT	ION			
If yes, select exemption:												Martin Library	Dimer	nsions (US n	nsmts.)	Volume	# B'
Other exemption - Write in:												Weight Lbs.	Depth	Height	Width	(Cube)	# Pieces:
Is product repackaged?			No		Yes, was origina	al product	t purchase	d direct			Item:			2.935	1.562		
Is product sold by manufactu Has FDA granted waiver/exce			No No		om mfr? yes, attach doci	umontatio	n from ED/				Box/Carton/Bundle/						
rias i DA granteu warver/exce	eption/exemption for	product:	110	• "	yes, allacii doci	umematio	11 110111 1 DA	٠.			Inner Pack:						
			GTIN PRODUCT INFOR	MATION							Case:	2.2	10.8	3.2	7	0.14	24
				Saleable								2.2	10.0	0.2	,	0.14	2-7
Serialized?	Yes	х	Level	Unit	X 2D		Linear	Quantity	GTIN-14 003317229300	117	Pallet:		48	6	40		220
If not, when?	162	1 x	Box/Carton/Bundle/Inner Pack	x	X 2D 2D		Linear	24	103317229300		UPC:	Case:					
Items aggregated?									Carton:								
	Pallet 20 Linear							-	WILOT ECAL ED HOE ONLY								
								COST	WHOLESALER USE ONLY:								
					2D		Linear				Regular Cost			Vendor #:			
					2D		Linear				Invoice Cost (WAC) (\$)			Whsl. Code			
											Federal Excise Tax Pe	r Unit of Sale		Fineline Co	de:		
											As of date:			-			
			Attach copy of SAFETY DA	TA SHEET (	SDS) or non haz-	ard letter	PACKAGE	INSERT I AF	SEL AND PHOT	O OF PRO	DUICT PACKAGING and B	ARCODE		1			
*Please provide any addition	al information on nac		Auton copy of OAI LIT DA	III OIILLI (	Jooj or non nazi				ron Shin Only	0 01 1 10	Signatu	ra·					



## **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): **SDS Hazard Classification** a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Organic Corrosive No 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: d. Packing Group e. Inhalation Hazard? REMS or REGISTRY RESTRICTIONS Is the product restricted for air shipment? If so, indicate restriction: Passenger Is there a REMS on this product? 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? Nο 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: 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 by Supplier: No SP# PCPDP #: NPI#: No ADD'L STORAGE INFORMATION Is the Product.. Comments Controlled Substance? Yes Controlled by State(s)? Yes Registry: ARCOS Reportable? Yes Registry Program Contact Name: Schedule No. (inc. N for non-narcotic) Comments CII - oxymorphone 9652 Controlled Substance Code Listed Chemical (List I or II) No RETURN INSTRUCTIONS If ves. 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: 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: 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 Yes	Purchase order daily receipt cut off time by supplier Cut off time: 2:30PM Eastern								
b. Autofax         No         Fax Number:           c. Fax         Yes         Fax Number:           d. Phone only         No         Phone No.:	Shipping lead time of PO: 24/48 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:  Yes								
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing								
Expedited freight fees billed with each order:  Drop Ship service fee billed with each order:  No	Overnight receipt available:  PO Receipt cut off time:  2:30PM  Eastern								
Drop Ship miscellaneous fees billed:  Comments:	Days of week overnight is available:								
	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 Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) No Comments:	Saturday Overnight receipt available:         No           PO Receipt Cut off time:           Phone #:           Phone:         Yes         Phone #:         Fax #:         732-562-8788           Fax #:         Yes         Overnight Fees apply:         Yes         No								
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?  No								