

# **Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)**

Version 2021						Introduction Ty	ype:	New Item		x Final Version			Date:	6/12	2/2024
			PRODUCT INFORMAT	ION						SPECIAL HA	ANDLING AND STOR	AGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA							ANDA	a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/ANDA/BLA (drug); PMA/510(K)/med device): 210175 and 25 C (68° – 77° F)															
Medical Device Class, if applical		, , , , , , , , , , , , , , , , , , ,	.,												
DUNS:	11-856-3719									Other Temperature Range	e Requirement				
Proprietary Name (If Applicable) a	and Established Na	me: Oxy	morphone Hydrochloride Tablets	s, USP 10 mg						(write in)	•				
Selling Unit NDC:	31722-930-01		Unit of Use NDC:			UPC:	3317229	330017		Notes					
UDI			CVX Code:			MVX Code:									
Description: Oxymorphone Hydrochloride Tablets, USP 10 mg								Is this product to be shipp	ed to customers on i	ce?		No	1		
								Is this product to be shipp	ed to customers on o	Iry ice?		No	1		
Active Ingredient(s): Oxymorphone hydrochloride, USP													-		
							b. Contact for temperature excursion questions:								
URL for Additional Product Inform		www.camberphar	ma.com							Name:		Soma Raju			
Address:	800 Centennial Av	re, Suite 1				Address 2:		00000		Number:		732-529-042			
City:	Piscataway Customer Service				State: Email:	NJ	Zip:		Group E-mail: somaraju@heterousa.c				neterousa.cor	<u>n</u>	
Key Contact: Phone Number:	1-866-827-3647				Fax:	r32-562-8788	campen	priamia.com	c. Special regulations for product in any states?					*Yes	7
Product Therapeutic Classification		Opioid agonist			l ux.	702 002 0700			c. opeciai re	Special returns requirement				*Yes	-
Froduct Therapeutic Classificatio	nı.	Opioid agoriist								Special returns requireme	ints for this product?			165	_
	ADDITIO	ONAL PRODUCT I	INFORMATION	_	_	PRODUCT D	ESCRIP	TION INFORMATION	d Store prod	luct (unit of sale) upright?				No	1
The manduct is 2	ADBITIC	J.W.E. 1.105001		Direct Shir C	nly	- 1 KODOO1 D		THE OTHER PROPERTY.	a. Store prod						1
The product is? a legend device?		No	Is the Product	Direct-Ship C Neither	nny .		4	00 ct	e. Shelf life:	Protect product (unit of	saie) from light?			No 24	Months
if yes, enter class #		INO	Orphan Drug Status	rveitriei		Size:	'	00 Cl	e. Shell life:	Initial shelf life at launch	(if different):			24	Months
a product kit?		No	Orphan Drug Status				1	0 mg		ilitiai sileli ille at laulici	i (ii dilierent).				Months
if yes, list NDCs of		140	FDA Approval Status			Strength:	'	o mg			ORDER INFORM	IATION			
component parts						Danama Farm	. Т	ablet							
reverse numbered?		No				Dosage Form	١-			Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present							x Bottle		1 Bottle of 1			
latex-free?		Yes	Lactose, Dairy, Dye, C		Animal,	Product Shap	e: R	Round, flat		Box/Carton		(Write-in, e.	.g. 1 Box of 1	0 Vials)	
preservative-free?		Yes	Rennet, Cas	sein, Whey						Ampule				_	
correctional institution block?		No				Product Colo	r: P	Pink		Glass		Minimum o	rder quantity	1?	Yes
opioid? Cannabinoid?		Yes	Country of Origin	USA			D	lehossed with 'T 278' on one side		Tube Vial Liquid Sgl					
If Unit Dose, is item bar coded to		No	Country of Origin	USA		Product Impri		nd plain on the other side		Vial Liquid Sgi		If Voc how	many of whi	ich package	typo?
hospital scanning?	unit dose for		Is this product covered un	der the						Vial Powder Sql			Each	icii package	type:
If Unit Dose, indicate NDC here:			Trade Agreements Act (TA		Yes					Vial Powder Mu			Inner/Cartor	n/Pack	
				,						Other: Write In			Case		
			FOR GENERIC DRUG PRO	DUCTS									-		
									1			-			
					Au	thorized Generic		orized Generic, other	PHARMACY ORDER / BILL UNIT						
I. Orange Book Rating:	AB			T			section f	fields are not applicable	Rec. sell unit	to customer?		Rx billing u	nit to pharm	acv:	
II. Generic Equivalent to What Bra	and?:	Opana											Each		
-									(Write-in, e.g	. 1 Vial)			Gram		
		DRUG SUP	PLY CHAIN SECURITY ACT (D	SCSA) INFOR	RMATION								Milliliter		
				т.							THE AND DANKING	IFOR!			
Does supplier meet DSCSA defini	ition of manufacture	er?	Yes		GLN:	0860000397957				ΙΤΙ	EM AND PACKING II	NFORMATIO	N		
Is product exempt from DSCSA?			No						1						
If yes, select exemption:					GCP:				1	Weight Lbs.		ons (US msr	-	Volume	Saleable #
Other exemption - Write in:			No								Depth	Width	Height	(Cube)	Pieces
Is product repackaged? Is product sold by manufacturer's		42	Yes	-	direct from m	riginal product purc	nased		Item/Each:	0.09	1.56	1.56	2.94	7.16	1
Has FDA granted waiver/exceptio			No	-		iir r ce manufacturer for	ronacks	aged product	Box/Carton/E	Rundle/					
If yes, attach documentation fro		ouuci:	110	1	r rovide sour	ce manufacturer for	гераска	ageu product	Inner Pack:	Juliule/					
ii yoo, attaon accamontation no									Case:		100	7			
		G	TIN AND HIBCC PRODUCT IN	FORMATION						2.2	10.8	/	3.2	241.92	24
									Pallet:						
Saleable Unit of Measure	Sa	aleable Quantity	HIBCC			N-14		Unit of Use GTIN-14							
X Item/Each		1			003	31722930017									
Box/Carton/Bundle/Inner Pack										COST INFORMATIO	N .		WHOLESAL	ER USE ONL	.Y:
X Case		24			103	31722930014			B						
Pallet					-				Regular Cost Invoice Cost		6470.00	Vendor #: Whsl. Code	#.		
									invoice Cost	(AAWC) (D)	\$170.00	Fineline Co			
									As of date:	4/30/2018		. memie co	uc.		
									713 Of Gale.	55/2515		1			
	_								1						
·			Attach copy of SAFETY DAT	A SHEET (SD	S) or non haza	ard letter, PACKAGE	INSERT.	LABEL AND PHOTO OF P	RODUCT PACK	AGING and BARCODE.					
				,											
*Please provide any additional inf	formation on page 2	2.				See new p. 3 for I	Designat	ted Drop Ship Only.		Signature:					



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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?  No  Does the product label bear a CA Prop 65 warning?  No	x 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	Does the product have an Aerosol class? If yes, identify NFPA Storage Level:  NFPA Storage Level:						
Is this product regulated for shipment by DOT?  (if yes, answer a-e below and provide SDS)  a. UN/Identification Number  b. Proper Shipping Name	Is the product a NIOSH hazardous drug?  If yes, indicate which:						
c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification						
e. Inhalation Hazard?  Is this product regulated for shipment by IATA?  No	EPA Hazardous Waste Code: Waste Characteristics						
(if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS						
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is there a REMS on this product?  If Yes, is it managed with a pharmacy registry?  Website URL:  Yes  No  https://opioidanalgesicrems.com/home.html						
Is the product restricted for air shipment? If so, indicate restriction:  Passenger  Cargo Passenger & Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)						
Is this a reportable quantity? No RQ Threshold: Is this a marrine pollutant? No Is this product shipped utilizing an authorized DOT exception or Special Permit?  No (if yes, identify method below) Limited Quantity Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4)	REMS:  REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier:  Yes Prathima Arrabelly Phone:  (631) 881-4614 Ext. 1412  DEA #: NCPDP#: NPI #:						
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments  Registry:  No						
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone:  Comments						
Is the Product							
Controlled Substance? Yes Controlled Substance Code   9652   Controlled by State(s)? Yes Listed Chemical (List I or II) No   ARCOS Reportable? Yes   If yes, indicate which:   2   Is it a scheduled listed chemical product?: No   CLASS OF TRADE RESTRICTION:	RETURN INSTRUCTIONS  Contact tel. # if product received damaged:  Is product returnable for credit:  URL/Link to returns policy:						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes	contact - customerservice@camberpharma.com						
Restricted to retail pharmacy only:  Restricted to hospital, clinics, and physician offices only:  Restricted from US territories? (explain in comments)  No	Special regulations or returns requirements for this product in certain states?  If so, which states? Other requirements? Comments?						
Comments:	DEA Form 222 or its electronic equivalent is required for all returns in all states.						
MISCELLAN	EOUS NOTES and/or Image of Product Barcode:						
*Storage of this product must abide by the federally mandated DEA requirements outlined in 21 CFR Pa	t 1301.72.						



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#### FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop S	nip 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:
b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	per:	Shipping lead time of PO:  Hours  Days  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 Designa	ed Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:  Drop Ship service fee billed with each order:		Overnight receipt available:  PO Receipt cut off time:
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, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	s and physician offices	Saturday Overnight receipt available:  PO Receipt Cut off time:  Phone: Fax: EDI:  Overnight Fees apply: Other fees apply:
Other Data Information Required to F	rocess PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # 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?