

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

Version 2024						Introduction T	ype: New Item		x Final Version			Date:	8/23/	/2024
			PRODUCT INFORMA	TION					SPECIAL HAN	IDLING AND STOR	AGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc.				Applicat		a. Temperatur	a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/AN	NDA/BLA; PMA/510	(k):	211487			NDA 505(b) Type:	NOT APPLICABLE		Temperature Range	Controlled Room		and 25 C (68	3° – 77° F)	
Medical Device Class, if applical	ble:													
DUNS:	11-856-3719								Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a		ime:	Hydrocodone Bitartrate and Acetar		ts, USP 7.5 mg				(write in)					
Selling Unit NDC:	31722-942-05		Unit of Use NDC:			UPC:	331722942058		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Hydrocodone Bita	rtrate and Ace	taminophen Tablets, USP 7.5 mg/3	325 mg					Is this product to be shippe				No	
									Is this product to be shippe	d to customers on o	Iry ice?		No	
Active Ingredient(s): Hydrocodone bitartrate, USP, acetaminophen, USP														
URL for Additional Product Inform	mation:	www.camber	pharma com						temperature excursion qu Name:	estions:	Soma Raju			
Address:	800 Centennial Av		priarria.com			Address 2:			Number:		732-529-042	23		
City:	Piscataway	o, cano i			State:	NJ	Zip: 08854	Group E-mail:			somaraju@heterousa.com			
Key Contact:	Customer Service	!			Email:	customerservice@	camberpharma.com		5.54F 2				_	
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special reg	ulations for product in any	states?			*Yes	1
Product Therapeutic Classificatio	on:	Combination opio	oid, and non-opioid, non-salicylate analgesic and	l antipyretic					Special returns requiremen	ts for this product?			*Yes	
					_									
	ADDITIO	ONAL PRODU	JCT INFORMATION			PRODUCT I	DESCRIPTION INFORMATION	d. Store produ	ct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship 0	Only				Protect product (unit of sa	ale) from light?			No	1
a legend device?		No	Is the Product	Neither		Size:	500 ct	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status			Size.			Initial shelf life at launch (if different):				Months
a product kit?		No				Strength:	7.5 mg/325 mg							
if yes, list NDCs of			FDA Approval Status							ORDER INFORM	IATION			
component parts reverse numbered?		No				Dosage Forn	Tablet		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present					-	x Bottle		1 Bottle of 5		unit.	
latex-free?		Yes		_			Capsule		Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		Yes	Cori	n, Dye		Product Sha	pe:		Ampule			•		
correctional institution block?		No				Product Cold	Off white/white		Glass		Minimum o	rder quantity	1?	Yes
opioid?		Yes				r routet con			Tube					
Cannabinoid?		No	Country of Origin	USA		Product Impi	Debossed 'T 258' on one side and plain on other side with bisect line		Vial Liquid Sgl					
If Unit Dose, is item bar coded to unhospital scanning?	unit dose for		In this was divided a second of	and an ellipse		·			Vial Liquid Multi Vial Powder Sal				ich package t	type?
If Unit Dose, indicate NDC here:			Is this product covered u Trade Agreements Act (Yes				Vial Powder Sgi Vial Powder Multi		12	Each Inner/Cartor	/Pack	
II Offit Dose, indicate NDC fiere.			Trade Agreements Act (1704):	163				Other: Write In			Case	I/I ack	
			FOR GENERIC DRUG PR	ODUCTS										
					Au	uthorized Generic	*If Authorized Generic, other		Pł	IARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AA						section fields are not applicable	Rec. sell unit	to customer?		Rx billing u	nit to pharm	асу:	
II. Generic Equivalent to What Bra	and?:	Norco					Each							
					(Write-in, e.g. 1 Vial) Gram									
		DRUG	SUPPLY CHAIN SECURITY ACT (DSCSA) INFO	RMATION			HCPCS J-Cod	e:			Milliliter		
Does supplier meet DSCSA defini	ition of manufactur	or?	Yes	_	GLN:	0860000397957			ITEN	AND PACKING II	VEORMATIO	N		
Is product exempt from DSCSA?			No	_	GLN.	0000000337337			** = "	I AND I ACIDITO II	II OKMATIO			
If yes, select exemption:					GCP:					Dimenei	ons (US msr	nte \	Volume	Saleable #
Other exemption - Write in:					GUF.				Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was o	riginal product pure	chased	Item/Each:			1			
Is product sold by manufacturer's	s exclusive distribu	itor?	Yes		direct from n				0.57	2.90	2.90	5.22	43.75	1
Has FDA granted waiver/exceptio	on/exemption for pr		No		Provide sour	ce manufacturer fo	r repackaged product	Box/Carton/Bi	undle/					
If yes, attach documentation from	m FDA.							Inner Pack:						
			GTIN AND HIBCC PRODUCT I	NEODMATION				Case:	7.5	12.1	9	5.5	598.95	12
			GTIN AND HIBCC PRODUCT II	NFORMATION				Pallet:						
Saleable Unit of Measure	RFID tag(Y/N)	Saleable	HIBCC		GTI	IN-14	Unit of Use GTIN-14	Pallet:						
Calcabio Cint of Micasars	Tti ID tag(1/14)	Quantity	TIIDOO		011		Cliff of OSC Cliff 14							
x Item/Each	N	1			003	31722942058								
Box/Carton/Bundle/Inner Pack									COST INFORMATION			WHOLESAL	ER USE ONL	.Y:
X Case	N	12			103	31722942055								
Pallet								Regular Cost			Vendor #:			
								Invoice Cost (WAC) (\$)	\$80.00	Whsl. Code Fineline Co			
								As of date:	12/10/2020		rineline Co	ue:		
								As of date.	12/10/2020		1			
							1							
			Attach copy of SAFETY DA	ATA SHEET (SI	OS) or non haza	ard letter, PACKAGE	INSERT, LABEL AND PHOTO C	F PRODUCT PACKA	GING and BARCODE.					



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HA	ZARD 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?	x Organic Corrosive						
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?	Does the product have an Aerosol class? If yes, No						
d. Does this product require special clean-up instructions?	identify NFPA Storage Level:						
(If yes, attach SDS with special instructions.)	NFPA Storage Level:						
e. Does the product contain DEHP?							
Is this product regulated for shipment by DOT?	Is the product a NIOSH hazardous drug?						
(if yes, answer a-e below and provide SDS)	If yes, indicate which:						
a. UN/Identification Number	n yee, malate milen.						
b. Proper Shipping Name							
c. DOT Hazard Class	Hazardous Waste Identification						
d. Packing Group							
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics						
Is this product regulated for shipment by IATA?							
(if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS						
a. UN/Identification Number	REIRO DI REGISTRI REGISTRI GIONO						
b. Proper Shipping Name	Is there a REMS on this product?						
c. DOT Hazard Class	If Yes, is it managed with a pharmacy registry?						
d. Packing Group	Website URL: https://opioidanalgesicrems.com/home.html						
e. Inhalation Hazard?	The state of C.						
	Mid-Orito Dominal						
Is the product restricted for air shipment? If so, indicate restriction:	Med Guide Required						
Passenger							
Cargo Passenger & Cargo	Comments / Details: (For example, iPledge program?)						
Is this a reportable quantity? No	REMS: Yes						
RQ Threshold:	REMS Program Manager Name: Prathima Arrabelly Phone: (631) 881-4614 Ext. 1412						
Is this a marine pollutant? No	Supplier Manages REMS registry exclusively:						
Is this product shipped utilizing an authorized DOT exception or Special Permit?	Wholesale distributor support:						
No (if yes, identify method below)	Provider Name: DEA #:						
Limited Quantity	Site Enrollment Number assigned by Supplier: NPI #:						
Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4)	by Supplier: NPI #:						
Special Permit; DOT-SP	Comments						
Special Provision (listed in Column 7 of 49 CFR 172.101);	Collinents						
SP#	Registry: No						
3r#							
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone:						
	Comments						
Is the Product							
Controlled Substance? Yes Controlled Substance Code 9193	RETURN INSTRUCTIONS						
Controlled by State(s)? Yes Listed Chemical (List I or II) No							
ARCOS Reportable? Yes If yes, indicate which:	Contact tel. # if product received damaged: 1-866-827-3647						
Schedule No. 2 Is it a scheduled listed chemical product?: No	Is product returnable for credit:						
CLASS OF TRADE RESTRICTION:	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: No	·						
	Special regulations or returns requirements for this product in certain states?						
Restricted to hospital, clinics, and physician offices only: No	les les						
Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?						
Comments:	DEA Form 222 or its electronic equivalent is required for all returns in all states.						
MISCELLANE	OUS NOTES and/or Image of Product Barcode:						
*Storage of this product must abide by the federally mandated DEA requirements outlined in 21 CFR Part							
5.5.3g5 5. 2.5 product muct abide by the reductary mandated DEA requirements outlined in 21 of K Part							



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

Order Method f	for Designated Drop Ship Product	Standard Order Receipt and Processing					
Purchase orders may be accepted by:		Purchase order daily receipt cut off time by supplier					
a. EDI		Cut off time:					
b. Autofax	Fax Number:						
c. Fax	Fax Number:	Shipping lead time of PO: Hours Days					
d. Phone only	Phone No.:						
e. Supplier Web Site only	Site Address:	Ships same day for next day receipt:					
Minimum Order Quantity:		Ships for second day receipt:					
Supplier's Customer Service Number:		Ships regular ground for 3-10 days receipt:					
Contracted 3PL company / contact #:	Name:						
	Phone:						
Expedited Freight Cha	rges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing					
Expedited freight fees billed with each order	r:	Overnight receipt available:					
Drop Ship service fee billed with each order	r:	PO Receipt cut off time:					
Drop Ship miscellaneous fees billed:		Days of week overnight is available: Monday					
Comments:		Tuesday					
		Wednesday					
		Thursday					
		Friday					
		Priority Overnight receipt available:					
Clas	ss of Trade Restriction:	PO Receipt Cut off time:					
No restriction: Select VES if sold to retail ph	narmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:					
Restricted to retail pharmacy only:	lamacy, mospitals, clinics and physician offices	PO Receipt Cut off time:					
Restricted to hospital, clinics, and physician	offices only	Phone: Phone #:					
Restricted from US territories? (explain in co	•	Order receipt method: Fax: Fax #:					
Comments:		EDI:					
		Overnight Fees apply:					
		Other fees apply:					
Other Data Info	ormation Required to Process PO:	Return Instructions					
Patient Procedure Date:		Contact # if product is received damaged:					
Physician Name:		Is product returnable for credit:					
Physician/Clinic Phone #		URL/Link to returns policy:					
Physician State License #							
Physician/Clinic DEA #:		Special regulations or returns requirements for this product in certain states?					
Physician/Clinic Specialty:		If so, which states? Other requirements? Comments?					
N	liscellaneous Notes:						
		ADDITIONAL INFORMATION					
		Is product order for scheduled patient procedure?					
		Is product order for restocking purposes?					
		is product order for restocking purposes:					