

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

Version 2024						Introduction Type	: New Item		x Final Version			Date:	8/23/	/2024
			PRODUCT INFORMAT	ION					SPECIAL HAN	IDLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	Camber Pharmac	euticals, Inc.				Application	ANDA	a. Temperature	- Indicate the USP temp	erature range for th	nis product.			
Application Number for NDA/ANI						NDA 505(b) Type:	NOT APPLICABLE		Temperature Range	Controlled Room -		and 25 C (68°	° – 77° F)	
Medical Device Class, if applicab									, ,					
DUNS:	11-856-3719								Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a		ame: Hydroco	odone Bitartrate and Acetam	inophen Tablet	s, USP 5 mg/3				(write in)					
Selling Unit NDC:	31722-996-05		Unit of Use NDC:				1722996051		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Hydrocodone Bita	artrate and Acetaminop	hen Tablets, USP 5 mg/325	mg					Is this product to be shippe	d to customers on ic	e?		No	
									Is this product to be shipped	d to customers on d	ry ice?		No	
Active Ingredient(s):		Hydrocodone bitartra	te, USP, acetaminophen, US	SP						_				
URL for Additional Product Information: www.camberpharma.com								temperature excursion qu	estions:	Soma Raju				
Address:	800 Centennial A		<u>com</u>			Address 2:			Name: Number:		732-529-042	2		
City:	Piscataway					p: 08854		Group E-mail:			eterousa.com	<u> </u>		
Key Contact:	Customer Service	9			Email:	customerservice@ca		Stroup E Intali.						
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special regu	lations for product in any	states?			*Yes	
Product Therapeutic Classification	1:	Combination opioid, and non	n-opioid, non-salicylate analgesic and a	antipyretic					Special returns requirement				*Yes	
	ADDITI	ONAL PRODUCT INFO	ORMATION			PRODUCT DES	CRIPTION INFORMATION	d. Store produ	ct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship O	nly				Protect product (unit of sa	ale) from light?		i	No	ĺ
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:	5 mg/325 mg							
if yes, list NDCs of			FDA Approval Status						ORDER INFORMATION					
component parts		NI.				Dosage Form:	Tablet		Unit of Sale		What is the	NDC selling	unit?	
reverse numbered? co-licensed?		No No	Allergens Present					Г	x Bottle		1 Bottle of 50		umr	
latex-free?		Yes					Capsule		Box/Carton			g. 1 Box of 10	(Vials)	
preservative-free?		Yes	Corn,	Dye		Product Shape:			Ampule		(, . <u> </u>		
correctional institution block?		No				Product Color:	Off white/white		Glass		Minimum or	der quantity	?	Yes
opioid?		Yes				Froduct Color.			Tube				'	
Cannabinoid?		No	Country of Origin	USA		Product Imprint:	Debossed 'T 257' on one side and plain on other side with bisect line		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for						plan of other side with block line		Vial Liquid Multi		If Yes, how		ch package t	type?
hospital scanning?			Is this product covered un Trade Agreements Act (Tr		Yes				Vial Powder Sgl Vial Powder Multi			Each	DI-	
If Unit Dose, indicate NDC here:			Trade Agreements Act (17	AA) r	Yes			-	Other: Write In			Inner/Carton/ Case	Раск	
			FOR GENERIC DRUG PRO	DUCTE				L	Other. Write in			Case		
			FOR GENERIC DRUG FRO	DUCIS										
					Au	thorized Generic *If	Authorized Generic, other		Pŀ	HARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AA			1			ction fields are not applicable	Rec. sell unit to				nit to pharma	cv:	
II. Generic Equivalent to What Bran		Norco		1				itee. sen unit t	o dustomer .		IXX Dilling ui	Each	cy.	
								(Write-in, e.g. 1	Vial)			Gram		
		DRUG SUPPLY	CHAIN SECURITY ACT (D	SCSA) INFOR	MATION			HCPCS J-Code):			Milliliter		
				_										
Does supplier meet DSCSA definit	ion of manufactu	rer?	Yes		GLN:	0860000397957			ITEN	AND PACKING IN	IFORMATION			
Is product exempt from DSCSA?			No											
If yes, select exemption:					GCP:				Weight Lbs.		ons (US msm	•	Volume	Saleable #
Other exemption - Write in:									110.9.11 2.001	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No Yes		If yes, was or direct from m	iginal product purchas	sed	Item/Each:	0.57	2.90	2.90	5.22	43.75	1
Is product sold by manufacturer's Has FDA granted waiver/exception			No	-		or r ce manufacturer for re	anakagad product	Box/Carton/Bu	ndlo/					
If yes, attach documentation from		- Journal - Jour	140		Frovide Source	Le manuracturer for re	packageu product	Inner Pack:	nuie/					
,,								Case:		10.1				
		GTIN	AND HIBCC PRODUCT IN	FORMATION					7.5	12.1	9	5.5	598.95	12
								Pallet:						
Saleable Unit of Measure	RFID tag(Y/N)	Saleable	HIBCC		GTII	N-14	Unit of Use GTIN-14							
		Quantity												
X Item/Each	N	1			0033	31722996051			COST INFORMATION			WHOLESALE	D LISE ON	v
Box/Carton/Bundle/Inner Pack X Case	N	12			103	31722996058			COST INFORMATION		· · · · · · ·	MIOLESALE	K USE UNL	.1.
Pallet	IN	12			103			Regular Cost			Vendor #:			
								Invoice Cost (V	VAC) (\$)	\$60.00	Whsl. Code	#:		
								i i			Fineline Cod	le:		
								As of date:	12/10/2020]			
1								<u> </u>						
			Attach copy of SAFETY DAT	TA SHEET (SD	S) or non haza		ERT, LABEL AND PHOTO OF P							
*Please provide any additional info	ormation on page	2.				See new p. 3 for Des	ignated Drop Ship Only.		Signature:					



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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	On the selection of the						
	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 must 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: