

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

Version 2024						Introduction Type:	New Item	[x Final Version			Date:	10/10	0/2024
			PRODUCT INFORMA	TION					SPECIAL HAI	NDLING AND STOP	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc.					Application:	ANDA	a. Temperature	a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/AN	DA/BLA; PMA/510(k):	217166				NDA 505(b) Type:	NOT APPLICABLE		Temperature Range	Controlled Room	- between 20	and 25 C (68	° – 77° F)	
Medical Device Class, if applicat														
DUNS:	11-856-3719								Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a		e: Ketorola	ac Tromethamine Injection, Unit of Use NDC:	USP 15 mg/mL ((Single-Dose V		722305259		(write in)					
Selling Unit NDC: UDI	31722-305-25		CVX Code:			UPC: 3317 MVX Code:	22305259		Notes					
-			1											1
Description:	Ketorolac I rometham	nine Injection, USP	15 mg/mL (Single-Dose Via	als)					Is this product to be shippe Is this product to be shippe				No No	-
Active Ingredient(s): Ketorolac tromethamine, USP							is this product to be shippe		ary ice :		NO			
								b. Contact for	temperature excursion qu	lestions:				
URL for Additional Product Inform		ww.camberpharma.	<u>com</u>						Name:		Soma Raju			
Address:	800 Centennial Ave, S	Suite 1			a	Address 2:			Number:		732-529-042			
City:	Piscataway				State: Email:	NJ Zip			Group E-mail:		somaraju@l	neterousa.cor	<u>n</u>	
Key Contact: Phone Number:	Customer Service 1-866-827-3647				Fax:	customerservice@cam 732-562-8788	berpharma.com	c Special requ	lations for product in any	/ states?			No	1
Product Therapeutic Classification		onsteroidal anti-infla	ammatory drug (NSAID)		i un	102 002 0100			Special returns requirement				No	-
Troduct merupeatie olassineation			annatory arag (rio, iib)						opeolar returns requiremen				110	
	ADDITION	AL PRODUCT INFO				PRODUCT DESC	RIPTION INFORMATION	d. Store produ	ct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship Or	nly			-	Protect product (unit of s	ale) from light?			No	ī
a legend device?	No	0	Is the Product	Unit Dose	,	0	25 x 1 mL single-dose,	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status			Size:	flip top vials		Initial shelf life at launch	(if different):				Months
a product kit?	No	0				Strength:	15 mg/mL per single-dose							
if yes, list NDCs of			FDA Approval Status			g	vial			ORDER INFOR	MATION			
component parts reverse numbered?	Ni					Dosage Form:	Sterile, clear solution		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?	No		Allergens Present					Г	Bottle			x 1 mL Single		
latex-free?	Ye						N/A		x Box/Carton			g. 1 Box of 1		
preservative-free?	Ye					Product Shape:			Ampule			•		
correctional institution block?	No	0				Product Color:	Slightly yellow		x Glass		Minimum o	rder quantity	?	Yes
opioid?	No								Tube					
Cannabinoid? If Unit Dose, is item bar coded to u	No	0	Country of Origin	India		Product Imprint:	N/A		x Vial Liquid Sgl Vial Liquid Multi		If Voc. how	many of whi	oh nookaaa	turno?
hospital scanning?	Ye	95	Is this product covered u	nder the					Vial Powder Sol			Each	ch package	typer
If Unit Dose, indicate NDC here:		1722-305-01	Trade Agreements Act (1		No				Vial Powder Mult	i		Inner/Carton	/Pack	
			4	L					Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
				г						HARMACY ORDER				
	10			_ L	Au		uthorized Generic, other ion fields are not applicable			HARMACT ORDER				
	AP	oradol				3001		Rec. sell unit t	o customer?		Rx billing u	nit to pharma	acy:	
II. Generic Equivalent to What Bran		JIAUUI						(Write-in, e.g.	1 Vial)	_		Each Gram		
		DRUG SUPPLY	CHAIN SECURITY ACT (DSCSA) INFORI	MATION			HCPCS J-Code				Milliliter		
									J1885			1		
Does supplier meet DSCSA definit	tion of manufacturer?		Yes	_	GLN:	0331722498975			ITE	M AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			No											
If yes, select exemption:					GCP:				Weight Lbs.		ions (US msr		Volume	Saleable #
Other exemption - Write in:			No		K		4	Here / Ceeh		Depth	Width	Height	(Cube)	Pieces
Is product repackaged? Is product sold by manufacturer's	exclusive distributor	2	No Yes		If yes, was or direct from m	iginal product purchase fr?		Item/Each:	0.44	3.4	3.4	2.21	25.55	1
Has FDA granted waiver/exception			No	-		 e manufacturer for repa	ackaged product	Box/Carton/Bu	indle/					
If yes, attach documentation from		I		-' i				Inner Pack:						
								Case:	8.95	11	11	5.5	665.5	18
		GTIN	AND HIBCC PRODUCT I	NFORMATION					0.00			2.0		
Saleable Unit of Measure		alaabla	HIBCC		GTI	J 14	Unit of Use GTIN-14	Pallet:						
Saleable Onit of Measure	RFID tag(Y/N) Sa	uantity	HIBCC		GTI	N-14	Unit of Use GTIN-14							
X Item/Each	N	1			003	31722305259								
Box/Carton/Bundle/Inner Pack									COST INFORMATION			WHOLESAL	ER USE ONL	LY:
X Case	N	18			203	31722305253								
Pallet								Regular Cost			Vendor #:			
								Invoice Cost (NAC) (\$)	\$93.75	Whsl. Code			
								As of date:	8/26/2024		Fineline Co	ue.		
								, io o. udio.						
			Attach copy of SAFETY DA	TA SHEET (SDS	6) or non haza	d letter, PACKAGE INSE	RT, LABEL AND PHOTO OF P	PRODUCT PACKAG	GING and BARCODE.					
*Please provide any additional infe	ormation on page 2.		Attach copy of SAFETY DA	TA SHEET (SDS	6) or non haza		RT, LABEL AND PHOTO OF P gnated Drop Ship Only.		GING and BARCODE.					

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Version 2024 For Designa	ted Drop Ship Only Products, Please Use Page 3					
MATERIAL HA	ZARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply): a. Cytotoxic? 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? 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? Is this product regulated for shipment by DOT? No	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No NFPA Storage Level: Image: Storage Level: Is the product a NIOSH hazardous drug? No					
(if yes, answer a-e below and provide SDS) a. UN/dentification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group	If yes, indicate which: Hazardous Waste Identification					
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics					
Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS) (if Unit for the North Context of the Nor	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? No If Yes, is it managed with a pharmacy registry? Website URL:					
Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	Med Guide Required No Limited Distribution Requirement Comments / Details: (For example, iPledge program?)					
Is this a reportable quantity? No RQ Threshold: Is this a marine 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: No REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: Phone: Wholesale distributor support: DEA #: Provider Name: NCPDP#: Site Enrollment Number assigned NPI #:					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	Comments					
SP#ADD'L STORAGE INFORMATION	Registry: No Registry Program Contact Name: Phone: Comments					
Is the Product Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS					
Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which: If Schedule No. Is it a scheduled listed chemical product?: No	Contact tel. # if product received damaged: 1-866-827-3647 Is product returnable for credit: Yes					
	URL/Link to returns policy:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes Restricted to retail pharmacy only: No	contact - customerservice@camberpharma.com Special regulations or returns requirements for this					
No No Restricted from US territories? (explain in comments) No	Special regulations of returns requirements for this product in certain states? If so, which states? Other requirements? Comments?					
Comments:						
MISCELLANE	OUS NOTES and/or Image of Product Barcode:					



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

Version 2024 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 Fax Number: c. Fax Fax Number: d. Phone only Phone No.: e. Supplier Web Site only Site Address: Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name:	Purchase order daily receipt cut off time by supplier Cut off time: 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:
Phone:	Overnight and Drivity Overnight DO Broossing
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: Drop Ship miscellaneous fees billed: Comments:	Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday
	Priority Overnight receipt available:
Class of Trade Restriction: 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) Comments:	PO Receipt Cut off time: PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: PO Receipt Cut off time: Phone: Order receipt method: Phone: Fax: EDI: EDI: Covernight Fees apply: Other fees apply: Image: Covernight Fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	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?