

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

						Introduction Type:	New Item		x Final Version			Date:	10/10/	/2024
			PRODUCT INFORMAT	ION					SPECIAL HAND	DLING AND STOR	AGE REQUIF	EMENTS*		
Company Name:	Camber Pharmac	euticals Inc				Application:	ANDA	a Temperature –	Indicate the USP tempe	rature range for th	nis product			
Application Number for NDA/ANI						NDA 505(b) Type:	NOT APPLICABLE			Controlled Room -		and 25 C (68°	– 77° F)	
Medical Device Class, if applicab		(1.1)						1	inporataro rtango			(
DUNS:	11-856-3719				1			Oth	her Temperature Range R	'equirement				
Proprietary Name (If Applicable) a		me Ketorola	c Tromethamine Injection, I	USP 30 mg/ml	(Single-Dose \	/ials)		ī	(write in)	.oquii omoni				
Selling Unit NDC:	31722-306-25	inc.	Unit of Use NDC:	OOI OO IIIg/IIIL	(Origic Dosc)		22306256	Not						
UDI			CVX Code:			MVX Code:		1						
	Katanda a Tarand	hamina lainathan HOD		1->				I I	this was done to be a ship and		- 0		NI.	
Description:	Ketorolac Frometr	namine Injection, USP	30 mg/mL (Single-Dose Via	ils)					this product to be shipped				No	ı
Active Ingredient(s):		Ketorolac tromethami	ine LICD					IS T	this product to be shipped	to customers on a	ry ice?	L	No	
Active ingredient(s):		Ketorolac tromethami	rie, USP					h Contact for tom	nperature excursion que	etione				
URL for Additional Product Inform	otion:	www.camberpharma.c	com						nperature excursion que ime:	stions:	Soma Raju			
Address:	800 Centennial Av		oom		1	Address 2:			ımber:		732-529-042	3		
City:	Piscataway	-,			State:	NJ Zip : 08854			oup E-mail:			eterousa.com		
Key Contact:	Customer Service	ice			Email:	customerservice@cam			oup E mail.		<u>oomaraja om</u>	0.000000.0001		
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special regulat	tions for product in any	states?			No	ı
Product Therapeutic Classification		Nonsteroidal anti-infla	ammatory drug (NSAID)						ecial returns requirements			İ	No	ı
Troduct merapeutic diassilication		Tronotoroidal anti mine	animatory arag (110/112)					Opt	colai retarris regali errierita	o for and product:		L	140	
	ADDITI	ONAL PRODUCT INFO	ORMATION			PRODUCT DESC	RIPTION INFORMATION	d Store product /	(unit of sale) upright?			Г	No	ı
= 1	ADDITIO	ONALT RODOUT IN		Discoul Ohio O	No.	T RODOOT DEGO	th Hole her onmation	l ' '	, , , ,			L	-	ı
The product is?			Is the Product	Direct-Ship O	niy				otect product (unit of sal	le) from light?			No	
a legend device?		No	Is the Product	Unit Dose		Size:	25 x 1 mL single-dose,	e. Shelf life:	d-1 -1 -16 191 1 1 69				24	Months
if yes, enter class #		No	Orphan Drug Status				flip top vials	init	tial shelf life at launch (if	rainerent):		L		Months
a product kit? if yes, list NDCs of		No	FDA Ammerical Status			Strength:	30 mg/mL per single-dose vial			ORDER INFORM	ATION			
component parts			FDA Approval Status				Sterile, clear solution			ORDER IN ORM	ATION			
reverse numbered?		No				Dosage Form:	Sterile, clear solution	Uni	it of Sale		What is the	NDC selling i	ınit?	
co-licensed?		No	Allergens Present						Bottle		1 Box of 25 >			
latex-free?		Yes	Allergens i resent				N/A		x Box/Carton			1. 1 Box of 10		
preservative-free?		Yes				Product Shape:			Ampule		(**************************************	, Box oo	riaio)	
correctional institution block?		No					Slightly yellow		x Glass		Minimum or	der quantity	, [Yes
opioid?		No				Product Color:	g, ,		Tube				L	
Cannabinoid?		No	Country of Origin	India			N/A		x Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for		,			Product Imprint:			Vial Liquid Multi		If Yes, how	nany of which	h package t	ype?
hospital scanning?		Yes	Is this product covered ur	nder the					Vial Powder Sql			Each		
If Unit Dose, indicate NDC here:		31722-306-01	Trade Agreements Act (T.	AA)?	No				Vial Powder Multi			Inner/Carton/	Pack	
			'						Other: Write In			Case		
			FOR GENERIC DRUG PRO	DDUCTS							1			
					Au		thorized Generic, other		PHA	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AP			7	Au		uthorized Generic, other on fields are not applicable	Rec. sell unit to c		ARMACY ORDER		it to pharma	cy:	
		Toradol			Au			Rec. sell unit to c		ARMACY ORDER		it to pharma	cy:	
I. Orange Book Rating: II. Generic Equivalent to What Brai								Rec. sell unit to c	ustomer?	ARMACY ORDER			cy:	
			CHAIN SECURITY ACT (I	DSCSA) INFOR					ustomer?	ARMACY ORDER		Each	cy:	
II. Generic Equivalent to What Brai	nd?:	DRUG SUPPLY	CHAIN SECURITY ACT (E	DSCSA) INFOR	RMATION	secti		(Write-in, e.g. 1 Vi	ial) J1885		Rx billing ur	Each Gram Milliliter	су:	
II. Generic Equivalent to What Brai	nd?:	DRUG SUPPLY	CHAIN SECURITY ACT (E	DSCSA) INFOR				(Write-in, e.g. 1 Vi	ial) J1885	ARMACY ORDER AND PACKING IN	Rx billing ur	Each Gram Milliliter	су:	
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II. Generic Equivalent to What Brand Does supplier meet DSCSA definit is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: is product repackaged?	nd?: tion of manufactur	DRUG SUPPLY	CHAIN SECURITY ACT (E Yes No	DSCSA) INFOR	RMATION GLN: GCP: If yes, was or	secti 0331722498975 riginal product purchase	on fields are not applicable	(Write-in, e.g. 1 Vi	ial) J1885 ITEM Weight Lbs.	AND PACKING IN Dimensie Depth	Rx billing ur IFORMATION DOES (US msm Width	Each Gram Milliliter ts.) Height	Volume (Cube)	Pieces
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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? 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?	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) a. UN/Identification Number	REMS or REGISTRY RESTRICTIONS					
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:					
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 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: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier: No Phone: DEA #: NCPDP#: NPI #:					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments					
ADD'L STORAGE INFORMATION	Registry: Registry Program Contact Name: Comments No Phone:					
Is the Product						
Controlled Substance Code Controlled by State(s)? ARCOS Reportable? Schedule No. No Controlled Substance Code Listed Chemical (List I or II) No If yes, indicate which: Is it a scheduled listed chemical product?: No CLASS OF TRADE RESTRICTION:	RETURN INSTRUCTIONS Contact tel. # if product received damaged: I-866-827-3647 Is product returnable for credit: Yes					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	URL/Link to returns policy: contact - customerservice@camberpharma.com					
Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: No	Special regulations or returns requirements for this product in certain states?					
Restricted from US territories? (explain in comments) No Comments:	If so, which states? Other requirements? Comments?					
MISCELLANE	DUS NOTES and/or Image of Product Barcode:					



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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 c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	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:
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: Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty: Miscellaneous Notes:	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?
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure? Is product order for restocking purposes?