

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

Version 2021						Introduction Typ	e: New Item		x Final Version			Date:	11/20	0/2024
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name:	Camber Pharmac	euticals, Inc.				Application	n: ANDA	a. Temperature -	- Indicate the USP tempe	rature range for th	his product.			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 216651					1		emperature Range	Controlled Room -		and 25 C (68	° – 77° F)			
Medical Device Class, if applicable:														
DUNS:	11-856-3719							Ot	her Temperature Range F	Requirement	Excursions p	permitted to 1	5° to 30°C (5	59° to 86°F)
Proprietary Name (If Applicable) as	nd Established Na	ame: Ketor	olac Tromethamine Tablets, I	JSP 10 mg				T	(write in)	•				
Selling Unit NDC:	31722-686-01		Unit of Use NDC:				31722686013	No	otes					
UDI			CVX Code:			MVX Code:								
Description: Ketorolac Tromethamine Tablets, USP 10 mg Is this product to be shipped to customers on ice? No									7					
•			<u>.</u>						this product to be shipped				No	1
Active Ingredient(s): Ketorolac tromethamine, USP						Ť l						_		
						b. Contact for ter	mperature excursion que	estions:						
URL for Additional Product Inform		www.camberpharn	na.com						ame:		Soma Raju			
Address:	800 Centennial A					Address 2:			umber:		732-529-042			
City:	Piscataway						Zip: 08854	G	roup E-mail:		somaraju@h	neterousa.com	<u>n</u>	
Key Contact:	1-866-827-3647					customerservice@ca	amberpharma.com						NI.	7
Phone Number:		Managar data and t	- (I (A O A D)		Fax:	732-562-8788		c. Special regulations for product in any states? Special returns requirements for this product?					No	-
Product Therapeutic Classification	1:	Nonsteroidal anti-i	nflammatory drug (NSAID)					Sp	pecial returns requirement	s for this product?			No	
	ADDITI	ONAL PROPUSTU	JEODMATION .			PROBLICT DE	CORUNTION INCORMATION	1						7
	ADDITI	ONAL PRODUCT II				PRODUCT DES	SCRIPTION INFORMATION	11	(unit of sale) upright?				No	_
The product is?			Is the Product	Direct-Ship C	nly				otect product (unit of sa	le) from light?			No	
a legend device?		No	Is the Product	Neither		Size:	100 ct	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status					ll In	itial shelf life at launch (i	f different):				Months
a product kit?		No	EDA Annanial Status			Strength:	10 mg			ORDER INFORM	MATION			
if yes, list NDCs of component parts			FDA Approval Status				Film-coated tablet			ORDER INFORM	IATION			
reverse numbered?		No				Dosage Form:	i iiii-coated tablet	116	nit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present					II	x Bottle		1 Bottle of 1			
latex-free?		Yes	_				Round, bevel edged,		Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		Yes	Alcohol, Da	airy, Lactose		Product Shape:	biconvex		Ampule		, , ,		,	
correctional institution block?		No				Product Color:	White to off-white		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Froduct Color.			Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint	Debossed with 'K' on one		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for					oddot impriin	side and 'H' on other side		Vial Liquid Multi		If Yes, how		ch package	type?
hospital scanning?			Is this product covered u					_	Vial Powder Sgl		24	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (IAA)?	No				Vial Powder Multi Other: Write In			Inner/Cartor	/Pack	
			FOR GENERIC DRUG PR	OBLICTO				<u> </u>	Other: write in			Case		
			FOR GENERIC DRUG PR	ODUCIS										
					Δ.,	thorized Generic *II	f Authorized Generic, other		PH	ARMACY ORDER	/ BILL LINIT			
	A.D.				Au		ection fields are not applicable	Rec. sell unit to		ARIMAGT GREEK				
	AB	Taxadal						Rec. sell unit to	customer?	ı	Rx billing u	nit to pharm	acy:	
II. Generic Equivalent to What Bran	na /:	Toradol						(Write-in, e.g. 1 \	/ial\			Each Gram		
		DRUG SUPP	LY CHAIN SECURITY ACT (DSCSA) INFOR	MATION			(vviite-iii, e.g. i v	riai)			Milliliter		
Does supplier meet DSCSA definit	ion of manufactur	rer?	Yes	T	GLN:	0331722498975			ITEM	AND PACKING IN	NFORMATIO	N		
Is product exempt from DSCSA?			No											
If ves. select exemption:					GCP:			i		Dimensi	ons (US msn	nts.)	Volume	Saleable #
Other exemption - Write in:									Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was or	iginal product purcha	sed	Item/Each:	0.11	1.56	1.56	3.11	7.57	1
Is product sold by manufacturer's	exclusive distribu	utor?	Yes		direct from m	ifr?	-		0.11	1.36	1.56	3.11	1.51	' '
Has FDA granted waiver/exception		roduct?	No		Provide source	ce manufacturer for re	epackaged product	Box/Carton/Bund	dle/					
If yes, attach documentation from	n FDA.							Inner Pack:						
								Case:	2.95	10	7	4.31	301.70	24
		GI	IN AND HIBCC PRODUCT I	NFORMATION										
Saleable Unit of Measure		Saleable Quantity	HIBCC		CTI	N-14	Unit of Use GTIN-14	Pallet:						
x Item/Each	3	1	ПВСС			31722686013	Onit of Ose GTIN-14							
Box/Carton/Bundle/Inner Pack				- 003				COST INFORMATION			WHOLESALER USE ONLY:			
X Case		24			203	31722686017								
Pallet					1			Regular Cost			Vendor #:			
	1							Invoice Cost (WA	AC) (\$)	\$56.47	Whsl. Code	#:		
								11			Fineline Co	de:		
								As of date:	12/1/2024					
1								Ц			<u> </u>			
l	_	_	Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza		SERT, LABEL AND PHOTO OF F							
*Please provide any additional info	ormation on page	2.				See new p. 3 for De	signated Drop Ship Only.	Si	gnature:					



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

Order Method fo	r Designated Drop Ship 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:	Fax Number: Fax Number: Phone No.: Site Address:	Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt:					
F	Name: Phone:	Ships regular ground for 3-10 days receipt:					
Expedited Freight Charg	ges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing					
Expedited freight fees billed with each order:		Overnight receipt available:					
Drop Ship service fee billed with each order:		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 only: Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician of Restricted from US territories? (explain in conficulty) Comments:	offices only:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:					
Other Data Infor	rmation Required to Process 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?					
Mis	scellaneous Notes:						
		ADDITIONAL INFORMATION					
		Is product order for scheduled patient procedure? Is product order for restocking purposes?					