

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

Version 2021						Introduction Type:	Post Launch Change		x Final Version			Date:	11/29	9/2024
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 215375								Temperature Range	Controlled Room		and 25 C (68	3° – 77° F)		
Medical Device Class, if applicable:														
DUNS:	11-856-3719								Other Temperature Range	Requirement	Excursions	permitted to 1	5° to 30°C (5	59° to 86°F)
Proprietary Name (If Applicable) a	and Established Na	me: Diclof	enac Potassium for Oral So		g			[(write in)					
Selling Unit NDC:	31722-046-32		Unit of Use NDC	:			722046329		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Diclofenac Potass	ium for Oral Solution	n, USP 50 mg					Ī	Is this product to be shippe	d to customers on i	ce?		No	
									Is this product to be shippe				No	
Active Ingredient(s): Diclofenac potassium, USP														
								b. Contact fo	r temperature excursion qu	estions:				
URL for Additional Product Inform		www.camberpharm	a.com						Name:		Soma Raju			
Address:	800 Centennial Av	e, Suite 1			Ctata	Address 2:	00054		Number: Group E-mail:		732-529-042			
City: Key Contact:	Piscataway Customer Service		State: NJ Email: customerser			customerservice@car	p: 08854			somaraju@heterousa.com				
Phone Number:	1-866-827-3647				Fax:	732-562-8788	inderpriamia.com	c Special rea	gulations for product in any	states?			No	1
Product Therapeutic Classification		Non-steroidal anti-	nflamatory drug (NSAID)					or opecial to	Special returns requirement				No	
Troduct merapeane classification	,,,,	Trom otorordar ana	mamatory aray (110/112)						opeoidi retarrio requiremen	is for this product:			140	_
	ADDITIO	ONAL PRODUCT IN	IFORMATION			PRODUCT DESC	CRIPTION INFORMATION	d. Store product (unit of sale) upright?						1
The product is?			Is the Product	Direct-Ship C	nly				Protect product (unit of sa	ula) from light?			No	1
a legend device?		No	Is the Product	Unit Dose	/illy		9 single dose packets	e. Shelf life:	Protect product (unit of Sa	ile) from light?			24	Months
if yes, enter class #		140	Orphan Drug Status			Size:	5 single dose packets	C. Onen me.	Initial shelf life at launch (if different):			2.4	Months
a product kit?		No					50 mg							
if yes, list NDCs of			FDA Approval Status			Strength:				ORDER INFORM	MATION			
component parts						Dosage Form:	Single dose packet containing							
reverse numbered?		No				Dosage i oiii.	buffered, soluble powder		Unit of Sale			NDC selling	unit?	
co-licensed?		No	Allergens Present						Bottle		1 Box of 9 F			
latex-free?		Yes		Corn		Product Shape:	N/A		x Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free? correctional institution block?		Yes					White to off-white		Ampule Glass		Minimum			Vee
opioid?		No No				Product Color:	write to oii-write		Tube		winimum o	rder quantity	,,	Yes
Cannabinoid?		No	Country of Origin	India			N/A		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for	.10	,g			Product Imprint:			Vial Liquid Multi		If Yes, how	many of whi	ich package	type?
hospital scanning?		Yes	Is this product covered	under the					Vial Powder Sgl			Each		••
If Unit Dose, indicate NDC here:		31722-046-31	Trade Agreements Act	TAA)?	No				Vial Powder Multi			Inner/Cartor	/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PF	RODUCTS										
					Au		Authorized Generic, other			IARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB					sec	tion fields are not applicable	Rec. sell unit	to customer?	-	Rx billing u	nit to pharm	асу:	
II. Generic Equivalent to What Bra	and?:	Cambia										Each		
		DRUG GURD	LY CHAIN SECURITY ACT	(Decea) INFOE	MATION			(Write-in, e.g	. 1 Vial)			Gram		
		DRUG SUFF	LI CHAIN SECURITI ACT	(DSCSA) INFOR	IWATION							Milliliter		
Does supplier meet DSCSA defin	ition of manufactur	er?	Yes	_	GLN:	0331722498975			ITEN	I AND PACKING II	NFORMATIO	N		
Is product exempt from DSCSA?			No	_	02.11	0001122100010								
If ves. select exemption:					GCP:			i		Dimensi	ions (US msr	nts)	Volume	Saleable #
Other exemption - Write in:					GCF.			1	Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If ves. was or	iginal product purchas	ed	Item/Each:						
Is product sold by manufacturer's	s exclusive distribu	tor?	Yes		direct from m				0.08	1.75	1.75	3.44	10.54	1
Has FDA granted waiver/exception	on/exemption for pr	oduct?	No		Provide sour	ce manufacturer for rep	packaged product	Box/Carton/E	Bundle/					
If yes, attach documentation fro	m FDA.							Inner Pack:						
								Case:	2.2	11.5	8	4.5	414	24
		GT	IN AND HIBCC PRODUCT	INFORMATION										
Saleable Unit of Measure	0	alaabla Ovaatitu	LUDCC		CTI	N 44	Unit of Une CTIN 44	Pallet:						
X Item/Each	S	aleable Quantity	HIBCC			N-14 31722046329	Unit of Use GTIN-14							
Box/Carton/Bundle/Inner Pack		,			003	022040023			COST INFORMATION			WHOLESAL	ER USE ON	_Y:
X Case		24			203	31722046323								
Pallet						-		Regular Cost	i		Vendor #:			
								Invoice Cost	(WAC) (\$)	\$350.06	Whsl. Code	#:		
											Fineline Co	de:		
								As of date:	12/1/2024					
ļ !								LL			 			
*Please provide any additional in	fa	•	Attach copy of SAFETY D	ATA SHEET (SD	or non haza		ERT, LABEL AND PHOTO OF F ignated Drop Ship Only.	PRODUCT PACK						
		,				see new n 3 tor Des	ionared Uron Shin Only		Signature:					



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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 for Designated Drop S	nip 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: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	per:	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 Designa	ed Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order:		Overnight receipt available: 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, hospitals, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	s and physician offices	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to F	rocess 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?
Miscellaneous Notes:		
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure? Is product order for restocking purposes?