

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

Version 2024							Introduction <sup>3</sup>	Type: Post La	unch Change		2 Final Version			Date:	6/24/	/2024
				PRODUCT INFORMA	TION						SPECIAL H	ANDLING AND STO	RAGE REQU	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA							a. Temperature – Indicate the USP temperature range for this product.									
Application Number for NDA/AN	DA/BLA; PMA/510	)(k):	090636				NDA 505(b) Type	NOT APPI	LICABLE		Temperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applical																
DUNS:	11-856-3719									,	Other Temperature Range	ge Requirement		permitted to 1	5°C to 30°C (	59°F to
Proprietary Name (If Applicable) a	31722-535-30	ame:	Tenofovi	ir Disoproxil Fumarate Tab Unit of Use NDC:	lets 300 mg	31722-535-30	UPC:	331722535304			(write in)		86°F)			
Selling Unit NDC: UDI	31722-333-30			CVX Code:		31722-333-30	MVX Code:	331722535304		+	Notes					
									No	1						
Description:	Tenorovir Disopro	oxii Fumarate	rablets 30	ou mg							Is this product to be ship				No No	
Active Ingredient(s): Tenofovir disoproxil fumarate										l						
									b. Contact for	r temperature excursion	questions:					
URL for Additional Product Inform		www.cambe	erpharma.c	<u>com</u>							Name:		Soma Raju			
Address:		nnial Ave, Suite 1			Address 2: State: NJ Zin: 08854				Number:				732-529-0423 somaraju@heterousa.com			
City: Key Contact:	Piscataway Customer Service				Email:	-	Zip: 08854 @camberpharma.co	·m		Group E-mail:	<u>somaraju@</u>	somaraju@neterousa.com				
Phone Number:	1-866-827-3647	5			Fax:	732-562-8788	ewcamberphaima.co	<u>1111</u>	c. Special red	ulations for product in a			No			
Product Therapeutic Classification				verse transcriptase inhibitor (NtR I	Is) and HBV	102 002 0100			Special regulations for product in any states:  Special returns requirements for this product?					No		
l location appeared of accompanies		reverse transcr	riotase inhibit	tor							Openia retarno reganon	onto for ano product.				l
	ADDITI	ONAL PROD	UCT INFO	DRMATION			PRODUCT	DESCRIPTION INFO	ORMATION	d. Store prod	uct (unit of sale) upright	?			No	
The product is?				Is the Product	Direct-Ship	Only					Protect product (unit o				No	İ
a legend device?		No	1	Is the Product	Unit of Use	,	Size:	30 ct		e. Shelf life:					24	Months
if yes, enter class #				Orphan Drug Status			Size.				Initial shelf life at laund	h (if different):				Months
a product kit?		No					Strength:	300 mg				ODDED INFOR	MATION			
if yes, list NDCs of component parts				FDA Approval Status			_	Film-coated	d to blot			ORDER INFOR	MATION			
reverse numbered?		No					Dosage For	m:	u tablet		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No		Allergens Present							x Bottle		1 Bottle of 3			
latex-free?		Yes					Product Sha	Almond			Box/Carton		(Write-in, e	.g. 1 Box of 1	0 Vials)	
preservative-free?		Yes					1 Todact One				Ampule					
correctional institution block?		No					Product Col	lor: White			Glass		Minimum o	rder quantity	?	Yes
opioid? Cannabinoid?		No No	-	Country of Origin	India			Dehossed w	vith 'H' on one		Tube Vial Liquid Sql					
If Unit Dose, is item bar coded to u	unit dose for	140	_	Country of Origin	india		Product Imp		23' on other side		Vial Liquid Mul	ti	If Yes, how	many of whi	ch package t	type?
hospital scanning?				Is this product covered u	nder the						Vial Powder Se		24	Each	<b> -</b>	76
If Unit Dose, indicate NDC here:				Trade Agreements Act (1	TAA)?	No					Vial Powder M			Inner/Carton	/Pack	
									Other: Write In			Case				
			F	FOR GENERIC DRUG PR	ODUCTS											
						Au	thorized Generic	*If Authorized Gen	eric other			PHARMACY ORDER	R / BILL UNIT			
I. Orange Book Rating:	AB						anonizoa conono	section fields are r		Rec sell unit	to customer?			init to pharm	acv:	
II. Generic Equivalent to What Brand?: Viread								itee. sen unit	Rx billing unit to pharmacy:							
II. Concine Equitation to What Branch.								(Write-in, e.g. 1 Vial) Gram				-				
		DRUG	SUPPLY	CHAIN SECURITY ACT (	DSCSA) INFO	RMATION				HCPCS J-Cod	de:			Milliliter		
		_		V	_							EM AND PACKING	NEODMATIO	N		
Does supplier meet DSCSA definit Is product exempt from DSCSA?	tion of manufactui	rer?		Yes No	-	GLN:	0331722498975				!!	EM AND PACKING	INFORMATIO	IN .		
				110		GCP:				}		<b>D</b> '	sions (US ms			
If yes, select exemption: Other exemption - Write in:						GCP:					Weight Lbs	Dimens Depth	Width	•	Volume (Cube)	Saleable # Pieces
Is product repackaged?				No		If yes, was or	riginal product pur	rchased		Item/Each:				Height		
Is product sold by manufacturer's	exclusive distribu	utor?		Yes		direct from m					0.14	1.6	1.6	3.33	8.52	1
Has FDA granted waiver/exception	n/exemption for pr			No		Provide sour	ce manufacturer fo	or repackaged prod	luct	Box/Carton/B	Sundle/					
If yes, attach documentation from	m FDA.									Inner Pack:						
			GTIN	AND HIBCC PRODUCT IF	JEOPMATION					Case:	3.7	10.25	7	4.5	322.88	24
			GTIN	ANDTIBOCTRODUCTII	W OKWATION					Pallet:						
Saleable Unit of Measure	RFID tag(Y/N)	Saleable		HIBCC		GTI	N-14	Unit of Us	se GTIN-14	l anot						
		Quantity														
x Item/Each		1	1			003	31722535304	00331722	2535304							
Box/Carton/Bundle/Inner Pack		-	1			200	21722525200				COST INFORMATIO	N		WHOLESALI	ER USE ONL	.Y:
X Case Pallet		24	•			203	31722535308			Regular Cost			Vendor #:			
1 and										Invoice Cost		\$30.00	Whsl. Code	e #:		
												\$50.00	Fineline Co			
										As of date:	7/26/2022					
1				Attach copy of SAFETY DA	TA CLIEFT (O	OC) h	ad lawar DACKAC	E INICEDE I ADEL A	ND BLIOTO CE S	DODUCT DACK	ACINIC and BARCORE					
*Please provide any additional info	ormation on nage	2	P	Allacii copy of SAFETY DA	IIA SHEET (SI	וט נפכ non naza		r Designated Dron S		RODUCT PACKA	Signature					



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

#### Version 2024

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION							
Is this product (check all that apply):								
a. Cytotoxic?	SDS Hazard Classification							
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	4							
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	ii yes, indicate which.							
b. Proper Shipping Name								
c. DOT Hazard Class	Hazardous Waste Identification							
d. Packing Group								
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics							
, ,	REMS or REGISTRY RESTRICTIONS							
(if yes, answer a-e below and provide SDS) a. UN/Identification Number	REMOUT REGISTRY RESTRICTIONS							
	Is there a REMS on this product?							
b. Proper Shipping Name c. DOT Hazard Class	If Yes, is it managed with a pharmacy registry?							
d. Packing Group	Website URL:							
e. Inhalation Hazard?	Website UKL.							
Is the product restricted for air shipment? If so, indicate restriction:	Med Guide Required No							
Passenger	Limited Distribution Requirement							
Cargo	Comments / Details: (For example, iPledge program?)							
Passenger & Cargo								
Is this a reportable quantity? No	REMS: No							
RQ Threshold:	REMS Program Manager Name: Phone:							
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 NCPDP#:							
Consumer Commodity, ORM-D	by Supplier: NPI #:							
Small Quantity (49 CFR 173.4)	Comments							
Special Permit; DOT-SP	Comments							
Special Provision (listed in Column 7 of 49 CFR 172.101);								
SP#	Registry: No							
ADDII CTODAGE INFORMATION	Registry Program Contact Name: Phone:							
ADD'L STORAGE INFORMATION	Comments							
Is the Product								
Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS							
Controlled by State(s)? No Listed Chemical (List I or II) No								
ARCOS Reportable? No If yes, indicate which:	Contact tel. # if product received damaged: 1-866-827-3647							
Schedule No. 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								
	Special regulations or returns requirements for this product in certain states?							
Restricted to hospital, clinics, and physician offices only:  No	, INO							
Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?							
Comments:								
MISCELLANEO	DUS 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  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?						