

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

Version 2021					Introduction 1	Туре:	New Item		x Final Version			Date:	5/18/	/2022
		PRODUCT INFORM	ATION						SPECIAL HAN	DLING AND STOR	AGE REQUIF	REMENTS*	*	
Company Name:	Camber Pharmaceuticals. In	ю.			Applica	tion:	ANDA	a. Temperature -	Indicate the USP tempe	rature range for t	his product.			
Application Number for NDA/AND			2018	806					nperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicab														
	82-677-4775							Oth	er Temperature Range F	Requirement				
Proprietary Name (If Applicable) ar	nd Established Name:	Emtricitabine and Tenofovir Disc	proxil Fumarate Tal	blets, 200mg/3	300mg				(write in)					
Selling Unit NDC:	31722-560-30	Unit of Use ND	:		UPC:	33172256	0306	Not	es					
UDI		CVX Code:			MVX Code:									
Description:	Oral Solid - tablet, capsule s	shaped, white to off white, lower punc	h 'H' and upper pun	ch '124'				ls ti	nis product to be shipped	to customers on id	ce?		No	1
									nis product to be shipped				No	
Active Ingredient(s): Emtricitabine and Tenofovir Disoproxil Fumarate								1						
								b. Contact for tem	perature excursion que	estions:				
URL for Additional Product Information								Nar			Soma Raju			
Address:	1031 Centennial Ave (and) 8	800 Centennial Ave, Suite 1			Address 2:				nber:		732-529-042			
	Piscataway			State:	NJ	Zip: 08		Gro	oup E-mail:		somaraju@	heterousa	i.com	
	Customer Service			Email:		ce@camb	erpharma.com			0			N	1
	1-866-827-3647			Fax:	732-562-8788				ons for product in any				No	
Product Therapeutic Classification								Spe	ecial returns requirement	s for this product?			No	
					PRODUCT	DECODIDE		1.0					Nu	1
	ADDITIONAL PRO	ODUCT INFORMATION			PRODUCT	DESCRIPTI	ON INFORMATION		unit of sale) upright?				No	1
The product is?		Is the Product	Direct-Ship On	ly	1				tect product (unit of sa	le) from light?			No	
a legend device?	No	Is the Product	Neither		Size:	300	t	e. Shelf life:					24	Months
if yes, enter class #	N1.	Orphan Drug Status			1	000)ma/200ma	Init	ial shelf life at launch (r aifferent):				Months
a product kit? if yes, list NDCs of	No	FDA Approval Status			Strength:	200)mg/300mg			ORDER INFORM				
component parts		FDA Approval Status				Ora	al Solid - Tablet			ORDER IN OR				
reverse numbered?	No				Dosage Form	m: 010		Uni	t of Sale		What is the	NDC selling	unit?	
co-licensed?	No	Allergens Present							x Bottle		1 bottle of 30			
latex-free?	Yes				Barrier Oh	Cap	osule Shaped		Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?	Yes				Product Sha	ipe:			Ampule			•		
correctional institution block?					Product Col	wh	ite to Off White		Glass		Minimum or	der quantity	?	Yes
opioid?	No				FIGURE CON	01.			Tube					
Cannabinoid?	No	Country of Origin	India		Product Imp	Lov	ver punch 'H' and Uppe		Vial Liquid Sgl					
If Unit Dose, is item bar coded to un	nit dose for								Vial Liquid Multi		If Yes, how		ch package	type?
hospital scanning?		Is this product covered							Vial Powder Sql			Each		
If Unit Dose, indicate NDC here:		Trade Agreements Ac	(IAA)?	No					Vial Power Multi Other: Write In			Inner/Carton Case	/Pack	
									Other: write in			Case		
		FOR GENERIC DRUG F	RODUCIS					_						
			Γ	Au	thorized Generic	*If Authori	zed Generic, other		PH	ARMACY ORDER				
	AB			Au	dinonized Generic		lds are not applicable	Bee cell white						
I. Orange Book Rating: II. Generic Equivalent to What Bran								Rec. sell unit to c	ustomer?	1	Rx billing ur	Each	acy:	
II. Generic Equivalent to what Bran	Iur:							(Write-in, e.g. 1 Vi	əl)			Gram		
	DRI	UG SUPPLY CHAIN SECURITY AC	(DSCSA) INFORM			_		(wine-in, e.g. 1 Vi	ui)			Milliliter		
								1						
Does supplier meet DSCSA definit	ion of manufacturer?	Yes		GLN:	0331722000000				ITEN	AND PACKING I	NFORMATION			
Is product exempt from DSCSA?		No												
If yes, select exemption:				GCP:						Dimensi	ons (US msm	nts.)	Volume	Saleable #
Other exemption - Write in:									Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?		No		f yes, was or	iginal product			Item/Each:	0.45		2			1
Is product sold by manufacturer's	exclusive distributor?	No			rect from mfr?				0.15		2	3.375		
Has FDA granted waiver/exception		No		Provide source	ce manufacturer fo	or repackag	ed product	Box/Carton/Bundl	e/					
If yes, attach documentation from	n FDA.							Inner Pack:						
								Case:	4.45	12	8.25	5		24
		GTIN AND HIBCC PRODUCT	INFORMATION											
Saleable Unit of Measure	Saleable Qu	uantity HIBCC		OT!	N-14		ait of Line OTIN 44	Pallet:						
x Item/Each	Saleable Qu				N-14 31722560306	U	nit of Use GTIN-14							
Rem/Each Box/Carton/Bundle/Inner Pack	1			003.	01122000000				COST INFORMATION			WHOLESAL	ER USE ONL	Y:
X Case	24			203	31722560300	-								
Pallet	24			2000				Regular			Vendor #:			
								Invoice Cost (WA	C) (\$)	\$30.00	Whsl. Code	#:		
								Ì Ì			Fineline Cod			
								As of date:			1			
											1			
		Attach copy of SAFETY	DATA SHEET (SDS) or non haza			ABEL AND PHOTO OF P							
*Please provide any additional info	ormation on page 2.				See new p. 3 for	r Designated	d Drop Ship Only.	Sig	nature:					

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

Version 2021 For Designated Drop Ship Only Products, Please Use Page 3							
	MATERIAL HAZA	ARD 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? 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 No No No No	X Organic Inorganic Steroid/Androgen Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level: Is the product a NIOSH hazardous drug?	DS Hazard Classification Corrosive Oxidizer Contact Hazard No				
(if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? Is this product regulated for shipment by IATA?	<u>No</u>	If yes, indicate which: No Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics					
(if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	No	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:	NO				
Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo Is this a reportable quantity? RQ Threshold: Is this a marine pollutant? No Is this product shipped utilizing an authorized DOT exception or Spe (if yes, identify method below) Limited Quantity Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4) Special Provision (listed in Column 7 of 49 CFR 172.101);	No	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?) REMS: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier: Comments	No Phone: DEA #:				
SP# ADD'L STORAGE INFORMATION Is the Product Controlled Substance? No Controlled Substance		Registry: Registry Program Contact Name: Comments	No Phone: Phone: RETURN INSTRUCTIONS				
Controlled substance ? No Controlled Substance Controlled Substance ? No Listed Chemical (List I ARCOS Reportable? No I fyes, indicate which Is it a scheduled liste CLASS OF TRADE RESTRICTION No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	or II) No d chemical product?: No	KE UKK INSTRUCTIONS Contact tel. # if product received damaged: 1-866-827-3647 Is product returnable for credit: Yes URL/Link to returns policy: contact - customerservice@camberpharma.com Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments? No					
	MISCELLANEOU	US NOTES and/or Image of Product Barcode:					



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Version 2021 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: Image: Comparison of the co
Class of Trade Restriction:	PO Receipt Cut off time:
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:	Saturday Overnight receipt available: PO Receipt Cut off time: Order receipt method: Phone: Fax: EDI: Overnight Fees apply: Other 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?