

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

Version 2021						Introduction Type:	New Item		X Final Version			Date:	5/17	7/2022
			PRODUCT INFORMA	TION					SPECIAL H	ANDLING AND STO	RAGE REQUI	REMENTS*		
Company Name:	Camber Pharmac	euticals, Inc.				Application:	ANDA	a. Temperatu	ure - Indicate the USP tem	perature range for	this product.			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):  Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)														
Medical Device Class, if applicable:														
DUNS:	82-677-4775							_	Other Temperature Rang	e Requirement				
Proprietary Name (If Applicable) a		ame: Efavi	renz, Emtricitabine and Teno		umarate Table			I	(write in)					
Selling Unit NDC:	31722-736-30		Unit of Use NDC:				722736305	11	Notes					
UDI			CVX Code:			MVX Code:		1						
Description:	Oral Solid-tablet,	capsule shaped, Wh	ite to off white, Lower punch	'H' and Upper P	unch'128'			Ţ	Is this product to be shipp	ed to customers on	ice?		No	1
								Is this product to be shipp	ed to customers on	dry ice?		No		
Active Ingredient(s): Efavirenz, Emtricitabine and Tenofovir Disoproxil Fumarate														
						b. Contact fo	or temperature excursion	questions:						
URL for Additional Product Inform		A ( l) 000 O l	and all Arra Code 4		1	A ddunan O.		+	Name:		Soma Raju	20		
Address: City:	Piscataway	Ave (and) 800 Cente	nniai Ave, Suite 1		State:	Address 2:	o: 08854	-	Number: Group E-mail:		732-529-042		. com	
Key Contact:	Customer Service					omerservice@camberpharma.com				somaraju@heterousa.com				
Phone Number:	1-866-827-3647	,			Fax:	732-562-8788	camberpharma.com	c. Special re	gulations for product in a	nv states?			No	1
Product Therapeutic Classification									Special returns requireme				No	
														1
	ADDITI	ONAL PRODUCT IN	FORMATION			PRODUCT DESC	CRIPTION INFORMATION	d. Store product (unit of sale) upright?					1	
The product is?			Is the Product	Direct-Ship C	Only			11	Protect product (unit of				No	1
a legend device?		No	Is the Product	Neither	,		30ct	e. Shelf life:	i rotect product (utilt of	ouie, ironi ligiti?			24	Months
if yes, enter class #		1	Orphan Drug Status	1010101		Size:	000.	S. Onen me.	Initial shelf life at launc	ı (if different):			2-7	Months
a product kit?		No				Ot an analysis	600mg/200mg/300mg			(				
if yes, list NDCs of			FDA Approval Status			Strength:				ORDER INFOR	MATION			
component parts						Dosage Form:	Oral Solid - Tablet							
reverse numbered?		No				Doddgo i oiiiii			Unit of Sale			NDC selling	unit?	
co-licensed?		No	Allergens Present				-		x Bottle		1 bottle of 3			
latex-free?		No				Product Shape:	Capsule		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	rder quantity	.2	Yes
opioid?		No				Product Color:	Writte to oil writte		Tube		William O	uer quantity	<i>,</i> :	162
Cannabinoid?		No	Country of Origin	India			Lower punch 'H' and Uppe		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for	110	,g			Product Imprint:			Vial Liquid Mult		If Yes, how	many of whi	ich package	type?
hospital scanning?			Is this product covered u	inder the					Vial Powder Sq			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (	TAA)?	No				Vial Power Mult	i		Inner/Cartor	n/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
				_	Au		Authorized Generic, other			PHARMACY ORDER	R / BILL UNIT			
I. Orange Book Rating:	AB					sec	tion fields are not applicable	Rec. sell uni	t to customer?	_	Rx billing u	nit to pharm	acy:	
II. Generic Equivalent to What Bra	and?:	Atripla										Each		
		DDIIC CUDD	LY CHAIN SECURITY ACT	(Decea) INFO	MATION			(Write-in, e.g	j. 1 Vial)			Gram		
		DRUG SUPP	LT CHAIN SECURITY ACT	DSCSA) INFOR	RMATION							Milliliter		
Does supplier meet DSCSA defini	ition of manufactu	rer?	Yes	$\neg$	GLN:	0331722000000			ІТ	EM AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			No	$\dashv$										
If ves. select exemption:					GCP:			i		Dimens	ions (US msn	nts )	Volume	Saleable
Other exemption - Write in:					GUF.			1	Weight Lbs.	Depth	Width	Height	(Cube)	#Pieces
Is product repackaged?			No		If ves. was or	riginal product purchase	ed	Item/Each:		Бери				
Is product sold by manufacturer's	s exclusive distrib	utor?	No		direct from m				0.2		2	3.6	0	1
Has FDA granted waiver/exceptio	n/exemption for p	roduct?	No	7	Provide sour	ce manufacturer for rep	ackaged product	Box/Carton/I	Bundle/				0	
If yes, attach documentation fro	m FDA.							Inner Pack:					0	
								Case:	5.5	12	4.75	8	0	24
		GT	IN AND HIBCC PRODUCT I	NFORMATION								_		
Saleable Unit of Measure					0.77			Pallet:					0	
X Item/Each		Saleable Quantity	HIBCC			N-14 31722736305	Unit of Use GTIN-14							
X Item/Each Box/Carton/Bundle/Inner Pack					003	31122130305			COST INFORMATIO	N		WHOLESAL	ER USE ONL	Y:
X Case		24			203	31722736309			OGOT IN OKMATIO	•		MIOLLOAL	LIT OOL ONE	
Pallet					200			Regular Cos	t		Vendor #:			
								Invoice Cost	(WAC) (\$)	\$150.00	Whsl. Code	#:		
								[]			Fineline Co			
								As of date:						
								[]						
<u> </u>								Ц						
		_	Attach copy of SAFETY D	ATA SHEET (SE	S) or non haza		ERT, LABEL AND PHOTO OF F	PRODUCT PACK						
*Please provide any additional inf	tormation on page	2.				See new p. 3 for Desi	gnated Drop Ship Only.		Signature:					



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For Designated Drop Ship Only Products, Please Use Page 3

MA	TERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION				
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	SDS Hazard Classification					
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?	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?	No No	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	No	Is the product a NIOSH hazardous drug? If yes, indicate which:	No			
c. DOT Hazard Class		Hazardous Waste Identification				
d. Packing Group e. Inhalation Hazard?	No	EPA Hazardous Waste Code:		Waste Characteristics		
Is this product regulated for shipment by IATA?	No	21711 data data 17 data data.		Waste Characteristics		
(if yes, answer a-e below and provide SDS)		REMS or REGISTRY RESTRICTIONS				
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	No	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)				
Is this a reportable quantity?  RQ Threshold:  Is this a marine pollutant?  Is this product shipped utilizing an authorized DOT exception or Special Permit?  (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	DEA #: NCPDP#: NPI #:		
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);		Comments				
SP#		Registry:	No	Dhama		
ADD'L STORAGE INFORMATION		Registry Program Contact Name: Comments		Phone:		
Is the Product						
Controlled Substance? Controlled by State(s)? ARCOS Reportable? Schedule No.  No Controlled Substance Code Listed Chemical (List I or II) If yes, indicate which: Is it a scheduled listed chemical product?:  CLASS OF TRADE RESTRICTION:	Listed Chemical (List I or II)  If yes, indicate which: Is it a scheduled listed chemical product?:  No		1-866-827-3647 Yes			
	Yes	URL/Link to returns policy:	rvice@camberpharma.com			
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Restricted to retail pharmacy only:	No		rvice@camberpriama.com			
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)	No No	Special regulations or returns requirements for this product in certain states?  If so, which states? Other requirements? Comments?				
Comments:	INU	n 30, which states: Other requirements? Comments?				
	SCELLANEC	DUS NOTES and/or Image of Product Barcode:				



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

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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?				