

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

Version 2021						Introduction Type	: New Item		x Final Version			Date:	2/4/	/2022
			PRODUCT INFORMA	TION					SPECIAL HAI	IDLING 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/AN	IDA/BLA (drug); PN	/IA/510(k)(med devi	ce):	203	347				Temperature Range	Controlled Room		and 25 C (68	3° – 77° F)	
Medical Device Class, if applicable:														
DUNS:	82-677-4775							_	Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a	and Established Na	me: Marav	viroc Tablets 150mg 60ct						(write in)					
Selling Unit NDC:	31722-579-60		Unit of Use NDC:				1722579605		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Oral Solid - tablet	oval shaped, white	to off white color, Upper: '62'	Lower: 'J'					Is this product to be shippe	d to customers on i	ice?		No	1
									Is this product to be shippe				No	1
Active Ingredient(s):		Maraviroc												
								b. Contact fo	or temperature excursion qu	estions:				
URL for Additional Product Inform								4	Name:		Soma Raju			
Address:		Ave (and) 800 Cente	nnial Ave, Suite 1		Ctata.	Address 2:		_	Number:		732-529-042			
City:	Piscataway Customer Service				State: Email:		ip: 08854	_	Group E-mail:		somaraju(<u>oneterous</u>	a.com	
Key Contact: Phone Number:	1-866-827-3647				Fax:	732-562-8788	Ocamberpharma.com	a Special re	gulations for product in any	ctatac?			No	7
Product Therapeutic Classification					ı ax.	732-302-0700		c. Special re	Special returns requiremen				No	-
Froduct Therapeutic Classificatio	nı.								Special returns requiremen	is for this product?			INU	_
	ADDITIO	ONAL PRODUCT IN	IFORMATION			PRODUCT DES	CRIPTION INFORMATION	d Store pro	duct (unit of sale) upright?				No	7
	7.55	51111 <u>2 </u>		Direct-Ship Or	ale.	1105001520		u. otore pro-						1
The product is?		NI.	Is the Product	Neither	шу		00-1		Protect product (unit of s	ale) from light?			No	
a legend device? if yes, enter class #		No	Is the Product Orphan Drug Status	Neitriei		Size:	60ct	e. Shelf life:	Initial shelf life at launch	(if different):				Months Months
a product kit?		No	Orphan Drug Status				150mg		illitiai Sileli ille at iauricii	(ii dillerent).				WOILLIS
if yes, list NDCs of		140	FDA Approval Status			Strength:	Toomg			ORDER INFOR	MATION			
component parts							Oral Solid - Tablet							
reverse numbered?		No				Dosage Form:			Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present					"	x Bottle		1 bottle of 6	0 tablets		
latex-free?		Yes				Product Shape:	Oval		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes				i roddot onapc.			Ampule					
correctional institution block?						Product Color:	White to Off White		Glass		Minimum o	rder quantity	/?	Yes
opioid?		No							Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint	Upper: '62' Lower: 'J'		Vial Liquid Sgl		W. W b			
If Unit Dose, is item bar coded to unhospital scanning?	unit dose for	No	Is this product covered of						Vial Liquid Multi Vial Powder Sql			Each	ich package	type?
If Unit Dose, indicate NDC here:		INO	Trade Agreements Act (No				Vial Powder Sqi Vial Power Multi		24	Inner/Cartor	/Book	
il Offit Dose, indicate NDC fiere.			Trade Agreements Act (174):	INU				Other: Write In			Case	// aux	
			FOR GENERIC DRUG PR	ODUCTS					Caron vincom			Joaco		
			TOR GENERIO BROSTI	.000010										
				[Au	thorized Generic *If	Authorized Generic, other		P	HARMACY ORDER	R / BILL UNIT			
I. Orange Book Rating:	AB						ction fields are not applicable	Rec sell uni	it to customer?		Rx billing u	nit to nharm	2011	
II. Generic Equivalent to What Bra		Selzentry						Tree. sen um	it to customer.		KX billing u	Each	acy.	
ii. Generic Equivalent to What Bra	iliu:.	Ocizonary						(Write-in, e.g	n. 1 Vial)			Gram		
		DRUG SUPP	LY CHAIN SECURITY ACT	(DSCSA) INFORI	MATION			(, , , , ,	,,			Milliliter		
				•										
Does supplier meet DSCSA defini	ition of manufactur	er?	Yes		GLN:	0331722000000			ITE	M AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			No											-
If yes, select exemption:					GCP:				Mainta III -	Dimens	ions (US msn	nts.)	Volume	# Pieces:
Other exemption - Write in:									Weight Lbs.	Depth	Width	Height	(Cube)	
Is product repackaged?			No			iginal product purcha	sed	Item/Each:	0.15	1.66	1.75	3.50		1
Is product sold by manufacturer's			No	_	direct from m									
Has FDA granted waiver/exceptio		oduct?	No	┙.	Provide sour	ce manufacturer for re	packaged product	Box/Carton/	Bundle/					
If yes, attach documentation fro	m FDA.							Inner Pack:	4.00	44.50	0.05	4.75		
		GT	IN AND HIBCC PRODUCT I	NEODMATION				Case:	4.20	11.50	8.25	4.75		24
		GI	IN AND HIBCC PRODUCT I	NFORMATION				Pallet:						
Saleable Unit of Measure	9	aleable Quantity	HIBCC		GTII	N-14	Unit of Use GTIN-14	railet.						3264
X Item/Each	3	1	7 IIDOO			31722579605	00331722579605							
Box/Carton/Bundle/Inner Pack					300				COST INFORMATION			WHOLESAL	ER USE ONL	Y:
X Case		24			203	31722579609								
Pallet								Regular Cos	st .		Vendor #:			
								Invoice Cost	t (WAC) (\$)	\$1,410.82	Whsl. Code	#:		
											Fineline Co	de:		
								As of date:			-			
<u> </u>						5.0//.5=		<u> </u>	/.o.v.o		<u> </u>			
	formation on page	_	Attach copy of SAFETY D	ATA SHEET (SDS	s) or non haza		SERT, LABEL AND PHOTO OF	PRODUCT PACK						
		,				See new n 3 for De	signated Drop Ship 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? 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? 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? 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	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)	REMS or REGISTRY RESTRICTIONS						
a. UN/Identification Number 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? (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#: NCPDP#: NPI #:						
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments						
	Registry: No Registry Program Contact Name: Phone:						
ADD'L STORAGE INFORMATION Is the Product	Comments						
Controlled Substance? 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	Contact tel. # if product received damaged: Is product returnable for credit: 1-866-827-3647						
CLASS OF TRADE RESTRICTION: No restriction: Select YES if sold to retail charmacy, hospitals, clinics and physician offices Yes	URL/Link to returns policy: contact - customerservice@camberpharma.com						
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: No	contact - customerservice@camberpnarma.com Special regulations or returns requirements for this product in certain states?						
Restricted from US territories? (explain in comments) Comments:	If so, which states? Other requirements? Comments?						
MISOFILA	ISOUS NOTES and/or Image of Dradust Parenday						
MISCELLA	NEOUS 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?