

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

Version 2021						Introduction Typ	Post Launch Change		x Final Version			Date:	5/30	/2024
			PRODUCT INFORMA	TION					SPECIAL HAP	NDLING 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): 203347								Temperature Range	Controlled Room		and 25 C (68	3° – 77° F)		
Medical Device Class, if applicable:														
DUNS:	11-856-3719								Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a	and Established Na	me: Mara	viroc Tablets 150 mg						(write in)					
Selling Unit NDC:	31722-579-60		Unit of Use NDC:		31722-579-60		31722579605		Notes					
UDI			CVX Code:			MVX Code:								
Description: Maraviroc Tablets 150 mg Is this product to be shipped to customers on ice? No									1					
-									Is this product to be shippe				No	
Active Ingredient(s):		Maraviroc												
								b. Contact for	or temperature excursion qu	estions:				
URL for Additional Product Inforn		www.camberpharm	na.com						Name:		Soma Raju			
Address:	800 Centennial Av	/e, Suite 1			State:	Address 2:	71		Number:		732-529-042			
City: Key Contact:	Piscataway Customer Service				Email:	customerservice@c	Zip: 08854		Group E-mail: somaraju@heterousa.com					
Phone Number:	1-866-827-3647	<u> </u>			Fax:	732-562-8788	amberphanna.com	c Special re	gulations for product in any	states?			No	1
Product Therapeutic Classificatio		Cyctaina-cyctaina che	emokine receptor 5 (CCR5) co-re	centor antagonist	ı ux.	702 002 0700		C. Special re	Special returns requirement				No	
Trouder Therapeutic Classificatio	//··	Cysteme Cysteme Cité	ciriokine receptor 5 (OONS) co-re	coptor antagoriist					Special returns requiremen	its for this product:			140]
	ADDITIO	ONAL PRODUCT IN	NEORMATION			PRODUCT DE	SCRIPTION INFORMATION	d Store pro	duct (unit of sale) upright?				No	1
	7,55111	51111 <u>2 </u>		Direct-Ship On	di c	1 1105001 52		a. otore pro]
The product is? a legend device?		No	Is the Product	Unit of Use	iiy		60 ct	e. Shelf life:	Protect product (unit of s	ale) from light?			No 24	Mantha
if yes, enter class #		INO	Orphan Drug Status	Offic of Ose		Size:	60 Ct	e. Shell life:	Initial shelf life at launch	(if different):			24	Months Months
a product kit?		No	Orphan Drug Status				150 mg		illitiai Sileli ille at iaulicii	(ii dillerent).				WIOTILIS
if yes, list NDCs of		140	FDA Approval Status			Strength:	100 mg			ORDER INFORM	MATION			
component parts						B	Film-coated 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	Dairy Lactos	e, Soy, Alcohol		Product Shape	Oval, biconvex		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes	Daily, Lucios	c, coy, Alcohol		i roundt Griupe			Ampule					
correctional institution block?		No				Product Color:	White to off-white		Glass		Minimum o	rder quantity	/?	Yes
opioid?		No					Debossed with '.l' on one side		Tube					
Cannabinoid?	and deep for	No	Country of Origin	India		Product Imprin	and '62' on the other side		Vial Liquid Sgl		K Vaa haw			
If Unit Dose, is item bar coded to unhospital scanning?	unit dose for		Is this product covered u	inder the				_	Vial Liquid Multi Vial Powder Sql			Each	ich package	type?
If Unit Dose, indicate NDC here:			Trade Agreements Act (No				Vial Powder Multi		24	Inner/Cartor	n/Pack	
ii onii bose, indicate Nbo nere.			Trade rigidements rick (.,,,	140				Other: Write In			Case	I/I dok	
			FOR GENERIC DRUG PR	ODUCTS]		
			1 011 021121110 01100 1 11											
				Γ	Autl	horized Generic *	If Authorized Generic, other		PI	HARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB						ection fields are not applicable	Rec. sell un	t to customer?		Py hilling u	nit to pharm	acv.	
II. Generic Equivalent to What Bra		Selzentry									ita billing u	Each	uoy.	
III Conono Equivalent to Tinat En		,						(Write-in, e.	ą. 1 Vial)			Gram		
		DRUG SUPP	LY CHAIN SECURITY ACT	(DSCSA) INFORM	MATION							Milliliter		
Does supplier meet DSCSA defini	ition of manufactur	er?	Yes		GLN:	0331722498975			ITEI	M AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			No											
If yes, select exemption:					GCP:				Weight Lbs.	Dimensi	ions (US msn	nts.)	Volume	# Pieces:
Other exemption - Write in:									Weight Lbs.	Depth	Width	Height	(Cube)	
Is product repackaged?			No			ginal product purch	ased	Item/Each:	0.15	1.6	1.6	3.34	8.55	1
Is product sold by manufacturer's			Yes	_	direct from mf									
Has FDA granted waiver/exceptio		oduct?	No		Provide sourc	e manufacturer for r	epackaged product	Box/Carton/	Bundle/					
If yes, attach documentation from	m FDA.							Inner Pack: Case:			-		-	
		GT	IN AND HIBCC PRODUCT I	NEORMATION				Case.	4.2	11.5	7.75	4.5	401.06	24
		01	IN AND HIDOUT NODOUT	IN OKMATION				Pallet:			+			
Saleable Unit of Measure	s	aleable Quantity	HIBCC		GTIN	I-14	Unit of Use GTIN-14	l ance.						
X Item/Each	•	1	111200			1722579605	00331722579605							
Box/Carton/Bundle/Inner Pack									COST INFORMATION			WHOLESAL	ER USE ONL	.Y:
x Case		24			2033	1722579609								
Pallet	_							Regular Cos			Vendor #:			
								Invoice Cos	(WAC) (\$)	\$1,410.82	Whsl. Code			
								11.	0/2/0000		Fineline Co	de:		
								As of date:	2/7/2022					
 			August convert CAFETY D	ATA CHEET (CO.	`\ a= a=a ba	dietter DACKACE II	ICEDT I ADEL AND DISCUSS	E DRODUCT DAGE	ACINC and DARCORS		1			
1			Attach copy of SAFETY Da	ATA SHEET (SDS	or non hazar		ISERT, LABEL AND PHOTO O esignated Drop Ship Only.	F PRODUCT PACE	AGING and BARCODE. Signature:					
*Please provide any additional inf	(•												



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Version 2021

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?