

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

Version 2021				Introduction Ty	Post Launch Change	X	Final Version			Date:	6/24/	/2024
		PRODUCT INFORMATION					SPECIAL HAN	DLING AND STOP	RAGE REQUI	REMENTS*	*	
Company Name:	company Name: Camber Pharmaceuticals, Inc. ANDA					a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/ANI			203047		·		ature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicab							Ū					
DUNS:	11-856-3719					Other Te	emperature Range I	Requirement				
Proprietary Name (If Applicable) a	nd Established Name:	Valacyclovir Tablets, USP 500 mg				(wr	ite in)					
Selling Unit NDC:	31722-704-30	Unit of Use NDC:	31722-704-30		331722704304	Notes						
UDI		CVX Code:		MVX Code:								
Description:	Valacyclovir Tablets, USP 500) mg					oduct to be shipped				No	
Is this product to be shipped to customers on dry ice? No										No		
Active Ingredient(s):	Valacyclov											
URL for Additional Braduct Inform	ation.					b. Contact for temperature excursion questions: Name: Soma Raju						
URL for Additional Product Inform Address:	800 Centennial Ave, Suite 1	erpharma.com		Address 2:		Name: Number			732-529-042	0		
City:	Piscataway		State:	NJ	Zip: 08854	Group E				.s ieterousa.cor	n	
Key Contact:	Customer Service				camberpharma.com					101010030.001		
Phone Number:	1-866-827-3647		Fax:	732-562-8788		c. Special regulations	for product in any	states?			No	1
Product Therapeutic Classification	n: Deoxynucl	eoside analogue DNA polymerase inhibitor	•			Special I	returns requirement	is for this product?			No	
								•				1
	ADDITIONAL PROD	DUCT INFORMATION		PRODUCT D	ESCRIPTION INFORMATION	d. Store product (unit of	d. Store product (unit of sale) upright? No					
The product is?		Is the Product Dir	ect-Ship Only			Protect	product (unit of sa	ale) from light?			No	1
a legend device?	No		it of Use	Size	30 ct	e. Shelf life:		,			24	Months
if yes, enter class #		Orphan Drug Status		Size:			nelf life at launch (if different):				Months
a product kit?	No			Strength:	500 mg							-
if yes, list NDCs of		FDA Approval Status		ouoligui				ORDER INFORM	MATION			
component parts		_		Dosage Form	Film coated tablet							
reverse numbered?	No	Allermone Dresent				Unit of S			1 Bottle of 3	NDC selling	unit?	
co-licensed? latex-free?	No Yes	Allergens Present			Capsule	x	Bottle Box/Carton			g. 1 Box of 10	0 \/iale)	
preservative-free?	Yes			Product Shap	e: Capsule		Ampule		(write-iii, e.	g. 1 Dox of 10	5 viais)	
correctional institution block?	No				Blue		Glass		Minimum or	der quantity	?	Yes
opioid?	No			Product Colo	r:		Tube					
Cannabinoid?	No	Country of Origin Ind	lia	Product Impri	Debossed with 'I' on one		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for			rioduct impli	side and '86' on other side		Vial Liquid Multi				ch package t	type?
hospital scanning?		Is this product covered under t					Vial Powder Sgl		24	Each		
If Unit Dose, indicate NDC here:		Trade Agreements Act (TAA)?	No				Vial Powder Multi			Inner/Carton	/Pack	
		FOR GENERIC DRUG PRODUC	270				Other: Write In			Case		
		FOR GENERIC DRUG PRODUC	515									
			Aut	horized Generic	*If Authorized Generic, other	PHARMACY ORDER / BILL UNIT						
I. Orange Book Rating:	AB				section fields are not applicable	Rec. sell unit to custor				nit to phorm	2014	
II. Generic Equivalent to What Brai	inge book Raling.					Rec. sell unit to customer? Rx billing unit to pharmacy:						
ii. Generie Equivalent to finat Bra	valio.					(Write-in, e.g. 1 Vial)				Gram		
	DRUG	G SUPPLY CHAIN SECURITY ACT (DSCS	SA) INFORMATION			(, , , , , , , , , , , , , , , , , , ,				Milliliter		
				-								
Does supplier meet DSCSA definit	tion of manufacturer?	Yes	GLN:	0331722498975			ITEN	I AND PACKING II	NFORMATIO	١		
Is product exempt from DSCSA?		No										
If yes, select exemption:			GCP:				Weight Lbs.		ions (US msm	,		Saleable #
Other exemption - Write in:		Na						Depth	Width	Height	(Cube)	Pieces
Is product repackaged?		No		ginal product purc	hased	Item/Each:	0.09	1.5	1.5	2.5	5.63	1
Is product sold by manufacturer's Has FDA granted waiver/exception		Yes No	direct from mi		repackaged product	Box/Carton/Bundle/						
If yes, attach documentation from		110	r Tovide Sourc		repackaged product	Inner Pack:						
						Case:	07	0.0	0.75	4.05	001.11	01
		GTIN AND HIBCC PRODUCT INFOR	MATION				2.7	9.8	6.75	4.25	281.14	24
						Pallet:						
Saleable Unit of Measure	Saleable Qua	ntity HIBCC	GTIN		Unit of Use GTIN-14							
X Item/Each	1		0033	1722704304	00331722704304							
Box/Carton/Bundle/Inner Pack				00004700704000			COST INFORMATION			WHOLESALER USE ONLY:		
X Case Pallet	24	-	2033	20331722704308		Regular Cost			Vendor #:	Vandar #		
- aner		-					Regular Cost Invoice Cost (WAC) (\$) \$24.43			#-		
	-					μ		ψ24.43	Fineline Co			
						As of date:	4/3/2017					
									1			
						1						
		Attach copy of SAFETY DATA S	HEET (SDS) or non hazar	d letter, PACKAGE	NSERT, LABEL AND PHOTO OF I	PRODUCT PACKAGING and	d BARCODE.					
	ormation on page 2.				Designated Drop Ship Only.	Signatu						

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Version 2021 For Designated Drop Ship Only Products, Please Use Page 3								
MATERIAL HA	ZARD 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? 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 Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) a. UN/Identification Number No No No No No No No N	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No NFPA Storage Level: Is the product a NIOSH hazardous drug? Is the product a NIOSH hazardous drug? No If yes, indicate which: If yes, indicate which:							
a. On/definition for holder b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? Is this product regulated for shipment by IATA? No	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Code:							
(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?	REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? No 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) Special Permit; DOT-SP	REMS: No REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: Phone: Wholesale distributor support: DEA #: Provider Name: DEA #: Site Enrollment Number assigned NCPDP#: by Supplier: NPI #:							
Special Provision (listed in Column 7 of 49 CFR 172.101); SP#ADD'L STORAGE INFORMATION	No Registry Program Contact Name: Comments							
Is the Product Controlled Substance? Controlled Substance? No Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which: Schedule No. Is it a scheduled listed chemical product?: No	RETURN INSTRUCTIONS Contact tel. # if product received damaged: 1-866-827-3647 Is product returnable for credit: Yes							
CLASS OF TRADE RESTRICTION: 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: No Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No Comments: No	Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments?							
MISCELLANE	OUS 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?