

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

Version 2021						Introduction Ty	/pe: Post L	aunch Change		x Final Version			Date:	6/24	1/2024
			PRODUCT INFORMA	TION						SPECIAL HAN	DLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	Camber Pharmace	euticals, Inc.				Application	on:	ANDA	a. Temperature	- Indicate the USP tempe	rature range for th	nis product.			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 203047							Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)								
Medical Device Class, if applicable:															
DUNS:	11-856-3719									ther Temperature Range F	Requirement				
Proprietary Name (If Applicable) as	nd Established Na	me: Valac	cyclovir Tablets, USP 1 gram							(write in)	•				
Selling Unit NDC:	31722-705-30		Unit of Use NDC:		31722-705-30		331722705301		N	lotes					
UDI			CVX Code:			MVX Code:									
Description: Valacyclovir Tablets, USP 1 gram Is this product to be shipped to customers on ice? No								1							
								this product to be shipped				No	1		
Active Ingredient(s): Valacyclovir hydrochloride, USP													-		
							b. Contact for to	emperature excursion que	estions:						
URL for Additional Product Inform		www.camberpharm	na.com							lame:		Soma Raju			
Address:	800 Centennial Av					Address 2:				lumber:		732-529-042			
City:	Piscataway				State:		Zip : 08854		Group E-mail: somaraju@heterousa.com						
Key Contact:	Customer Service 1-866-827-3647				Email:	customerservice@	camberpharma.c	com_							
Phone Number:		D		16-16	Fax:	732-562-8788			c. Special regulations for product in any states?						-
Product Therapeutic Classification	1:	Deoxynucleoside a	analogue DNA polymerase inf	nibitor						pecial returns requirement	s for this product?			No	_
	ADDITIO	ONAL PRODUCT IN	JECOMATION			PROPUST D	EGODIDTION IN	FORMATION							7
	ADDITIO	ONAL PRODUCT IN				PRODUCT DE	ESCRIPTION INF	FORMATION	1	t (unit of sale) upright?				No	_
The product is?			Is the Product	Direct-Ship C	Only					rotect product (unit of sa	le) from light?			No	
a legend device?		No	Is the Product	Unit of Use		Size:	30 ct		e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status						"	nitial shelf life at launch (f different):				Months
a product kit?		No	FDA Ammanual Status			Strength:	1 gram		ORDER INFORMATION						
if yes, list NDCs of component parts			FDA Approval Status				Film coate	ad tablet			ORDER INFORM	ATION			
reverse numbered?		No				Dosage Form:	: I'llill Coale	ed tablet	1 .	Init of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present							x Bottle		1 Bottle of 30			
latex-free?		Yes	,				Capsule			Box/Carton			g. 1 Box of 10) Vials)	
preservative-free?		Yes				Product Shape	e:			Ampule			,	,	
correctional institution block?		No				Product Color	White to o	off-white		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Froduct Color				Tube					
Cannabinoid?		No	Country of Origin	India		Product Impri		d with 'I' on one		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for					oaaotp	side and '8	87' on other side		Vial Liquid Multi		If Yes, how		ch package	type?
hospital scanning?			Is this product covered u						_	Vial Powder Sgl			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (1	AA)?	No				-	Vial Powder Multi Other: Write In			Inner/Carton	/Pack	
			FOR GENERIC DRUG PR							Other: write in			Case		
			FOR GENERIC DRUG PR	ODUCIS											
					Auth	norized Generic	*If Authorized Ge	paric other		PH	ARMACY ORDER	/ BILL LINIT			
	AB				Aut		section fields are		Rec. sell unit to		AKIIIAOT OKDEK				
		Valtrex							Rec. sell unit to	customer?	1	Rx billing ur		acy:	
II. Generic Equivalent to What Bran	iur:	vaillex							(Write-in, e.g. 1	Vial)			Each Gram		
		DRUG SUPP	LY CHAIN SECURITY ACT (DSCSA) INFO	RMATION				(vviite-iii, e.g. i	viai)			Milliliter		
				, ,											
Does supplier meet DSCSA definit	ion of manufactur	er?	Yes		GLN:	0331722498975				ITEN	I AND PACKING IN	IFORMATION			
Is product exempt from DSCSA?			No												
If ves. select exemption:					GCP:						Dimensio	ons (US msm	its.)	Volume	Saleable #
Other exemption - Write in:										Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was orig	ginal product purch	hased		Item/Each:	0.16	2	2	3.5	14.00	1
Is product sold by manufacturer's	exclusive distribu	tor?	Yes		direct from mf	r?				0.16	2	2	3.3	14.00	' '
Has FDA granted waiver/exception		oduct?	No		Provide source	e manufacturer for	repackaged pro	duct	Box/Carton/Bur	idle/					
If yes, attach documentation from	n FDA.								Inner Pack:						
			IN AND HIDOO BEODUCT II	JEODMATION.					Case:	4.4	12.5	8.5	4.5	478.13	24
		GI	IN AND HIBCC PRODUCT I	NFORMATION					B-11-4						
Saleable Unit of Measure	c	aleable Quantity	HIBCC		GTIN	14	Unit of U	Jse GTIN-14	Pallet:						
x Item/Each	3	1	ПВСС			1722705301		22705301							
	Box/Cartor/Bundle/Inner Pack					0000112			WHOLESALER USE ONLY:						
X Case		24			2033	1722705305				COST INFORMATION					
Pallet									Regular Cost			Vendor #:			
									Invoice Cost (W	AC) (\$)	\$38.88	Whsl. Code	#:		
]								1			Fineline Cod	le:		
									As of date:	4/3/2017		[
]								1			1			
1									<u> </u>			<u> </u>			
		_	Attach copy of SAFETY DA	TA SHEET (SI	OS) or non hazard										
*Please provide any additional info	armation on nage '	,				See new p. 3 for D		Shin Only		ignature:					



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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? 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 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?					