

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

Version 2021						Introduction Type:	: Post Launch Change		x Final Version			Date:	11/20	0/2024
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STO	RAGE REQUI	REMENTS*		
Company Name:	Camber Pharmace	euticals, Inc.				Application:	ANDA	a. Temperatu	re - Indicate the USP temp	erature range for	this product.			
Application Number for NDA/AN	IDA/BLA (drug); PM	A/510(k)(med devi	ce):	20516	6				Temperature Range	Controlled Room		and 25 C (68	3° – 77° F)	
Medical Device Class, if applica								İ						
DUNS:	11-856-3719								Other Temperature Range	Requirement	Excursions	permitted bet	ween 15° and	d 30°C (59°
Proprietary Name (If Applicable) a	and Established Nai	me: Valga	inciclovir Tablets, USP 450 m						(write in)		and 86°F)			
Selling Unit NDC:	31722-832-60		Unit of Use NDC:	31	722-832-60		1722832601		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Valganciclovir Tab	lets, USP 450 mg						Ī	Is this product to be shippe	d to customers on	ice?		No	7
	_								Is this product to be shippe				No	1
Active Ingredient(s):		Valganciclovir hydr	rochloride, USP											
								b. Contact fo	r temperature excursion qu	estions:				
URL for Additional Product Inform		www.camberpharm	na.com						Name:		Soma Raju			
Address:	800 Centennial Av	e, Suite 1			01-1-	Address 2:	00054		Number:		732-529-042			
City:	Piscataway Customer Service				State: Email:	NJ Zi customerservice@car	p: 08854		Group E-mail:		somaraju@h	eterousa.com		
Key Contact: Phone Number:	1-866-827-3647					732-562-8788	nberpharma.com	a Special re-	gulations for product in any	ctatos?			No	7
Product Therapeutic Classification		Decymucalosida a	analogue CMV DNA polymera	see inhibitor	ı ax.	732-302-0700		c. Special re	Special returns requirement				No	-
Product Therapeutic Classification	on:	Deoxyriuceioside a	analogue Civiv DIVA polymera	ise iririibitoi					Special returns requiremen	is for this product?			INO	_
	ADDITIC	NAL PRODUCT IN	JEORMATION			PRODUCT DESC	CRIPTION INFORMATION	d Store proc	luct (unit of sale) upright?				No	7
	ADDITIO	DNALTRODUCTIN		Discoul Obias Oak		PRODUCT DESC	CRIF FIGH IN GRIMATION	u. Store proc						4
The product is?			Is the Product	Direct-Ship Only					Protect product (unit of sa	ile) from light?			No	
a legend device? if yes, enter class #		No	Is the Product	Unit of Use		Size:	60 ct	e. Shelf life:	le Well about the action about	· · · · · · · · · · · · · · · · · · ·			24	Months Months
a product kit?		No	Orphan Drug Status				450 mg		Initial shelf life at launch (ii dinerent):				Wonths
if yes, list NDCs of		INO	FDA Approval Status			Strength:	430 mg			ORDER INFOR	MATION			
component parts			1 Divinpioral Glatag				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				Product Shape:	Oval, biconvex		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes				r roduct onape.			Ampule					
correctional institution block?		No				Product Color:	Pink		Glass		Minimum o	rder quantity	/?	Yes
opioid?		No							Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint:	Debossed 'J' on one side and '156' on the other side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for		In this was dead account to	and an the		•	and 156 on the other side		Vial Liquid Multi				ich package	type?
hospital scanning?			Is this product covered u Trade Agreements Act (Vial Powder Sgl Vial Powder Multi		24	Each	·/Deals	
If Unit Dose, indicate NDC here:			Trade Agreements Act (IAA)!)				Other: Write In			Inner/Cartor Case	I/Pack	
			FOR GENERIC DRUG PR	ODUCTS				1	Other: Write in			Ousc		
			TOR GENERIC DROGTR	000013										
					Auth	norized Generic *If /	Authorized Generic, other		PH	IARMACY ORDER	R / BILL UNIT			
I Oronno Book Betimer	AB			_	7100		ction fields are not applicable	Pac sall unit	t to customer?					,
I. Orange Book Rating: II. Generic Equivalent to What Bra		Valcyte					•••	ixec. sen uni	to customer:	1	KX billing u	nit to pharm Each	acy:	
II. Generic Equivalent to What Bra	anur.	vaicyte						(Write-in, e.g	1 Vial)			Gram		
		DRUG SUPPI	LY CHAIN SECURITY ACT (DSCSA) INFORMA	ATION			(**************************************				Milliliter		
				•										
Does supplier meet DSCSA defin	ition of manufacture	er?	Yes	GI	LN:	0331722498975			ITEN	I AND PACKING I	INFORMATIO	N		
Is product exempt from DSCSA?			No											
If yes, select exemption:				G	CP:			1	,	Dimens	ions (US msr	nts.)	Volume	Saleable #
Other exemption - Write in:								· [Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No	lf :	yes, was orig	ginal product purchas	ed	Item/Each:	0.15	1.75	1.75	3.5	10.72	1
Is product sold by manufacturer's			Yes	_	rect from mfr					1.75	1.75	3.5	10.72	'
Has FDA granted waiver/exception		oduct?	No	Pr	ovide source	e manufacturer for rep	packaged product	Box/Carton/E	Bundle/					
If yes, attach documentation fro	m FDA.							Inner Pack:						
		CT.	IN AND HIBCC PRODUCT I	NEODMATION				Case:	4.25	11	7.5	4.25	350.63	24
		GII	IN AND RIBCC PRODUCT II	NFORMATION				Pallet:			-		-	
Saleable Unit of Measure	c,	aleable Quantity	HIBCC		GTIN	14	Unit of Use GTIN-14	Pallet:						
X Item/Each	36	1	TIBOO			1722832601	00331722832601							
Box/Carton/Bundle/Inner Pack					0000		00001122002001		COST INFORMATION			WHOLESAL	ER USE ONL	LY:
X Case		24			2033	1722832605								
Pallet					7.00			Regular Cos	t		Vendor #:			
								Invoice Cost		\$250.00	Whsl. Code	#:		
											Fineline Co			
								As of date:	12/1/2024		_			
								[]						
								1.1			1			
1								L.						
*Please provide any additional in			Attach copy of SAFETY DA	ATA SHEET (SDS)	or non hazard		ERT, LABEL AND PHOTO OF Fignated Drop Ship Only.	PRODUCT PACK	AGING and BARCODE. 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. Cvtotoxic? 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? 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: Group 2 items (non-antineoplastic that meets a hazard criterion)					
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 DEA #: NCPDP#: NPI #:					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments Registry: No					
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:	Contact tel. # if product received damaged: Is product returnable for credit: URL/Link to returns policy:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	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) Comments:	If so, which states? Other requirements? Comments?					
MISCELLANE	OUS 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?					