

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

Version 2024						Introduction	Type: Ne	ew Item		x Final Version			Date:	11/1/	/2024
			PRODUCT INFORMA	ΓΙΟΝ						SPECIAL HAN	IDLING AND STOP	RAGE REQUI	REMENTS*		
Company Name:	Camber Pharmace	euticals, Inc.				Applica	ation:	ANDA	a. Temperature	- Indicate the USP tempe	erature range for t	his product.			
Application Number for NDA/ANI	DA/BLA; PMA/510(	(k): 21147	5			NDA 505(b) Type	NOT APPL	ICABLE		emperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicab	ole:								ĺ.						
DUNS:	11-856-3719								C	ther Temperature Range I	Requirement		are permitted	to 15°C to 30	0°C (59°F to
Proprietary Name (If Applicable) a		me: Valgar	nciclovir for Oral Solution 50	mg/mL						(write in)		86°F).			
Selling Unit NDC:	31722-837-10		Unit of Use NDC:		31722-837-10		331722837101		N	otes		Store dry powder solution under ref	at 20°C to 25°C (68 rigeration at 2°C to	8°F to 77°F); Store r 8°C (36°F to 46°F)	reconstituted for no longer than
UDI			CVX Code:			MVX Code:						49 davs. Do not f			
Description:	Valganciclovir for	Oral Solution 50 mg/	/mL							this product to be shipped				No	
									ls	this product to be shipped	d to customers on o	dry ice?		No	
Active Ingredient(s):		Valganciclovir free	base												
URL for Additional Product Inform	ation	www.camberpharma	a.com							mperature excursion qu ame:	estions:	Soma Raiu			
Address:	800 Centennial Av		<u>u.com</u>			Address 2:				umber:		732-529-042	23		
City:	Piscataway				State:	NJ	Zip: 08854			roup E-mail:			heterousa.cor	n	
Key Contact:	Customer Service				Email:	customerservice	@camberpharma.con	<u>m</u>		•				_	
Phone Number:	1-866-827-3647				Fax:	732-562-8788			c. Special regula	ations for product in any	states?			No	]
Product Therapeutic Classification	n:	Deoxynucleoside analogue	e cytomegalovirus (CMV) DNA polyme	ase inhibitor					S	pecial returns requirement	ts for this product?			No	
															_
	ADDITIC	ONAL PRODUCT IN	FORMATION			PRODUCT	DESCRIPTION INFO	ORMATION	d. Store product	t (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship (	Dnly				Р	rotect product (unit of sa	ale) from light?			No	1
a legend device?		No	Is the Product	Unit of Use		Size:	100 mL (afte		e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status			0.20.	reconstitutio	,	Ir	itial shelf life at launch (	if different):				Months
a product kit?		No	FD4 4			Strength:	50 mg/mL (a reconstitutio				ORDER INFORM				
if yes, list NDCs of			FDA Approval Status			_					ORDER INFORM	ATION			
component parts reverse numbered?		No				Dosage For	m: Powder for c	oral solution	u	nit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present							x Bottle			Bottle of Powd		olution
latex-free?		Yes	J. J			Des des colo	N/A			x Box/Carton			.g. 1 Box of 1		
preservative-free?		No				Product Sha				Ampule					
correctional institution block?		No				Product Co	White to slightly y for reconstitution	yellow powder blend		x Glass		Minimum o	rder quantity	?	Yes
opioid?		No							_	Tube					
Cannabinoid?	- 11 - 1	No	Country of Origin	India		Product Imp	orint: N/A		_	Vial Liquid Sgl		W. Y			
If Unit Dose, is item bar coded to u hospital scanning?	init dose for		Is this product covered u	ndor the						Vial Liquid Multi Vial Powder Sgl		12 12	many of whi Each	cn package	type?
If Unit Dose, indicate NDC here:			Trade Agreements Act (		No				-	Vial Powder Multi		12	Inner/Cartor	/Pack	
				,.					-	Other: Write In			Case	in doit	
			FOR GENERIC DRUG PR	ODUCTS											
					Au	thorized Generic	*If Authorized Gene	eric, other		PH	IARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB						section fields are no	ot applicable	Rec. sell unit to	customer?		Rx billing u	nit to pharm	acv:	
II. Generic Equivalent to What Bran	nd?:	Valcyte											Each		
									(Write-in, e.g. 1		_		Gram		
		DRUG SUPPL	LY CHAIN SECURITY ACT (	DSCSA) INFO	RMATION				HCPCS J-Code:		-		Milliliter		
			Vaa		<u> </u>	0004700 0000							N		
Does supplier meet DSCSA definit	tion of manufactur	er?	Yes	-	GLN:	0331722498975				ITEN	AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			No												
If yes, select exemption:					GCP:					Weight Lbs.		ions (US msr		Volume	Saleable #
Other exemption - Write in:			No		16	inimal une durat			16 mm / 17 1-		Depth	Width	Height	(Cube)	Pieces
Is product repackaged? Is product sold by manufacturer's	avalueiva dietriku	tor?	No Yes	-	If yes, was or direct from m	iginal product pu	cnased		Item/Each:	0.39	2.83	2.06	5.27	30.72	1
Has FDA granted waiver/exception			No				or repackaged produ	uct	Box/Carton/Bun	die/					
If yes, attach documentation from					e.iac sourc	- manadotarer r			Inner Pack:						
									Case:	5.2	11.75	7.3	6.5	557.54	12
		GTI	IN AND HIBCC PRODUCT II	FORMATION						5.2	11.75	1.5	0.5	557.54	12
									Pallet:						
					GTI	N-14	Unit of Use	e GTIN-14							
Saleable Unit of Measure	RFID tag(Y/N)		HIBCC												
		Quantity	HIBCC		000	24702027404	000047000	027101							
X Item/Each	RFID tag(Y/N)		HIBCC		003	31722837101	003317228	837101		COST INFORMATION					<b>v</b> .
X Item/Each Box/Carton/Bundle/Inner Pack	N	Quantity 1	HIBCC		-		003317228	837101		COST INFORMATION			WHOLESAL	ER USE ONL	_Y:
X Item/Each		Quantity			-	31722837101 31722837105	003317228	837101	Regular Cost	COST INFORMATION		Vendor #:	WHOLESAL	ER USE ONL	-Y:
x Item/Each     Box/Carton/Bundle/Inner Pack     Case	N	Quantity 1			-		003317228	837101	Regular Cost Invoice Cost (W	COST INFORMATION	\$600.00	Vendor #: Whsl. Code	WHOLESAL	ER USE ONL	-Y:
x Item/Each     Box/Carton/Bundle/Inner Pack     Case	N	Quantity 1			-		003317228	837101			\$600.00				Y:
X Item/Each     Box/Carton/Bundle/Inner Pack     Case	N	Quantity 1			-		003317228	837101		COST INFORMATION AC) (\$) 1/30/2023	\$600.00	Whsl. Code		ER USE ONL	-Y:
X Item/Each     Box/Carton/Bundle/Inner Pack     Case	N	Quantity 1			-		003317228	837101	Invoice Cost (W		\$600.00	Whsl. Code			Y:
X Item/Each     Box/Carton/Bundle/Inner Pack     Case	N	Quantity 1			203	31722837105			Invoice Cost (W	1/30/2023	\$600.00	Whsl. Code		ER USE ONL	Y:
X Item/Each     Box/Carton/Bundle/Inner Pack     Case	N N	Quantity	HIBCC	TA SHEET (SI	203	31722837105 rd letter, PACKAGI		ND PHOTO OF F	As of date:	1/30/2023	\$600.00	Whsl. Code		ER USE ONL	Y:

## HDA🔾

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

Version 2024 For Designation	ated 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?  Is this product regulated for shipment by DOT?  No	Does the product have an Aerosol class? If yes, identify NFPA Storage Level:       No         NFPA Storage Level:       Image: Storage Level:         Is the product a NIOSH hazardous drug?       Yes
(if yes, answer a-e below and provide SDS)       a. UN/Identification Number       b. Proper Shipping Name       c. DOT Hazard Class       d. Packing Group	If yes, indicate which: Group 2 items (non-antineoplastic that meets a hazard criterion) Hazardous Waste Identification
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics
Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name	REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? No
c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	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 No 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	REMS:     No       REMS Program Manager Name:     Phone:       Supplier Manages REMS registry exclusively:     Phone:       Wholesale distributor support:     Provider Name:       Provider Name:     DEA #:       Site Enrollment Number assigned     NCPDP#:       by Supplier:     NPI #:
Small Quantity (49 CFR 173.4) Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	Comments
SP#	Registry:     No       Registry Program Contact Name:     Phone:
ADD'L STORAGE INFORMATION Is the Product	Comments
Controlled Substance?       No       Controlled Substance Code         Controlled by State(s)?       No       Listed Chemical (List I or II)       No         ARCOS Reportable?       No       If yes, indicate which:	RETURN INSTRUCTIONS       Contact tel. # if product received damaged:     1-866-827-3647       Is product returnable for credit:     Yes
CLASS OF TRADE RESTRICTION:	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: No	Special regulations or returns requirements for this
Restricted to hospital, clinics, and physician offices only:       No         Restricted from US territories? (explain in comments)       No	product in certain states? No No If so, which states? Other requirements? Comments?
Comments:	
	EOUS NOTES and/or Image of Product Barcode:
Each bottle can deliver up to a total of 88 mL of solution. Each bottle is supplied with a bottle adapter and	2 oral dispensers.



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

Version 2024 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       Fax Number:         c. Fax       Fax Number:         d. Phone only       Phone No.:         e. Supplier Web Site only       Site Address:         Minimum Order Quantity:       Supplier's Customer Service Number:         Contracted 3PL company / contact #:       Name:	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:
Phone:	Overnight and Drivity Overnight DO Broossing
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:       PO Receipt cut off time:       Days of week overnight is available:       Monday       Tuesday       Wednesday       Thursday       Friday
	Priority Overnight receipt available:
Class of Trade Restriction:         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:	PO Receipt Cut off time:       PO Receipt Cut off time:         Saturday Overnight receipt available:       PO Receipt Cut off time:         PO Receipt Cut off time:       Phone:         Order receipt method:       Phone:         Fax:       EDI:         EDI:       Covernight Fees apply:         Other fees apply:       Image: Covernight 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?