

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

Version 2021						Introduction Type	: Post Launch Change		x Final Version			Date:	6/23	3/2024
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application:							a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/AN	IDA/BLA (drug); PI	MA/510(k)(med devi	ce):	20	3834			1	Temperature Range			loom – betwe	en 20 and 25	5 C (68° – 77°
Medical Device Class, if applica								Ť l						
DUNS:	11-856-3719							_	Other Temperature Range	Requirement	Store between	en 15° and 2	5° C.	
Propriet Is the product a CA Prop 6		cant? Acycl	ovir Tablets, USP 800 mg					I	(write in)					
Selling Unit NDC:	31722-778-05		Unit of Use NDC:				1722778053		Notes					
UDI			CVX Code:			MVX Code:		1						
Description:	Acyclovir Tablets	, USP 800 mg						I	Is this product to be shipped	d to customers on i	ce?		No	
									Is this product to be shipped	d to customers on	dry ice?		No	
Active Ingredient(s): Acyclovir, USP														
URL for Additional Product Information: www.camberpharma.com							b. Contact for temperature excursion questions:  Name:  Soma Raju							
Address:	800 Centennial A		a.com		T	Address 2:		+	Number:		732-529-042	23		
City:	Piscataway	ve, oute i			State:		<b>p</b> : 08854	1	Group E-mail:		somaraju@he			
Key Contact:	Customer Service	9			Email:	customerservice@camb		1						
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special re	gulations for product in any	states?			No	7
Product Therapeutic Classification	on:	Synthetic nucleosis	de analogue antiviral					_	Special returns requirement	s for this product?			No	1
					_									_
	ADDITI	ONAL PRODUCT IN	NFORMATION			PRODUCT DES	CRIPTION INFORMATION	d. Store prod	duct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship C	Only				Protect product (unit of sa	ile) from light?			No	7
a legend device?		No	Is the Product	Neither		Size:	500 ct	e. Shelf life:		-			24	Months
if yes, enter class #			Orphan Drug Status			Size.			Initial shelf life at launch (	if different):				Months
a product kit?		No				Strength:	800 mg							
if yes, list NDCs of			FDA Approval Status							ORDER INFOR	MATION			
component parts reverse numbered?		INI.				Dosage Form:	Tablet		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No No	Allergens Present						x Bottle		1 Bottle of 5		uiiit:	
latex-free?		Yes	Ancigons i resent				Oval, biconvex		Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		Yes				Product Shape:			Ampule		(	3	,	
correctional institution block?		No				Product Color:	Blue		Glass		Minimum o	rder quantity	/?	Yes
opioid?		No				Froduct Color.			Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint:	Debossed with 'J' on one side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for						and '50' on the other side		Vial Liquid Multi				ich package	type?
hospital scanning?			Is this product covered u						Vial Powder Sql		6	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (	IAA)?	No				Vial Powder Multi Other: Write In			Inner/Cartor Case	1/Pack	
			FOR GENERIC DRUG PR	ODUCTS				1	Other. Write in			Case		
			TOR GENERIC DROGTR	000013										
					Au	thorized Generic *If	Authorized Generic, other		Pŀ	IARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB						ction fields are not applicable	Rec. sell uni	t to customer?		Ry hilling u	nit to pharm	acv.	
II. Generic Equivalent to What Bra		Zovirax						1		1	TX Dilling u	Each	uoy.	
							(Write-in, e.g	ı. 1 Vial)			Gram			
		DRUG SUPP	LY CHAIN SECURITY ACT	(DSCSA) INFOR	RMATION							Milliliter		
1		_	.,,	_										
Does supplier meet DSCSA defini		rer?	Yes No	_	GLN:	0331722498975			IIEN	I AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			INU					-						
If yes, select exemption:					GCP:				Weight Lbs.		ions (US msn		Volume	Saleable #
Other exemption - Write in: Is product repackaged?			No		If was was s	riginal product purchas	and .	Item/Each:	-	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?	s avelusiva distribi	utor?	Yes	-	direct from m		ed	item/Each:	1.4	3.75	3.75	8	112.5	1
Has FDA granted waiver/exception			No	-		 ce manufacturer for rej	packaged product	Box/Carton/l	Bundle/					
If yes, attach documentation fro								Inner Pack:						
								Case:	9	12	8	9	864	6
		GT	IN AND HIBCC PRODUCT I	NFORMATION						12		, ,	004	0
II								Pallet:						
Saleable Unit of Measure	8	Saleable Quantity	HIBCC			N-14	Unit of Use GTIN-14							
X Item/Each Box/Carton/Bundle/Inner Pack		1			003	31722778053			COST INFORMATION			WHOLESAL	ER USE ONL	۱ V·
X Case		6			203	31722778057			- COOT IN ORMATION			MOLLOAL	EN OOL ON	
Pallet		U			203	5ZE110031		Regular Cos	t		Vendor #:			
								Invoice Cost		\$105.88	Whsl. Code	#:		
											Fineline Co			
								As of date:	4/15/2024					
ļ.								Ц						
		_	Attach copy of SAFETY D	ATA SHEET (SE	OS) or non haza		ERT, LABEL AND PHOTO OF F	PRODUCT PACK						
*Please provide any additional inf	formation on page	2.				See new p. 3 for Des	ignated Drop Ship Only.		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. 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?  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:						
c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification  EPA Hazardous Waste Code:  Waste Characteristics						
e. Inhalation Hazard?  Is this product regulated for shipment by IATA?  No	EPA Hazardous waste Code:						
(if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS						
a. UN/Identification Number 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 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  No  Phone:  DEA #: NCPDP#: NCPDP#: NPI #:						
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments						
56#	Registry:  Registry Program Contact Name:  Phone:						
ADD'L STORAGE INFORMATION	Comments						
Is the Product  Controlled Substance?  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	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:  Restricted to hospital, clinics, and physician offices only:  Restricted from US territories? (explain in comments)  No	Special regulations or returns requirements for this product in certain states?  If so, which states? Other requirements? Comments?						
Comments:							
MISCELLANI	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 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?