

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

Version 2021						Introduction Type:	Post Launch Change		x Final Version			Date:	6/1/2	2024
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/AN	NDA/BLA (drug); PN	/IA/510(k)(med device	ce):	203	3834				Temperature Range	Controlled Room		and 25 C (68	3° – 77° F)	
Medical Device Class, if applica			·						· -					
DUNS:	11-856-3719								Other Temperature Range	Requirement	Store between	en 15° and 2	5° C.	
Proprietary Name (If Applicable)	and Established Na	me: Acyclo	ovir Tablets, USP 400 mg						(write in)					
Selling Unit NDC:	31722-777-01		Unit of Use NDC:				22777018		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Acyclovir Tablets,	USP 400 mg							Is this product to be shippe	d to customers on i	ce?		No	1
									Is this product to be shippe				No	1
Active Ingredient(s):		Acyclovir, USP												
								b. Contact for	r temperature excursion qu	estions:				
URL for Additional Product Inform		www.camberpharma	i.com						Name:		Soma Raju			
Address:	800 Centennial Av	/e, Suite 1			State:	Address 2: NJ Zip:	00054		Number:		732-529-042			
City: Key Contact:	Piscataway Customer Service				Email:	customerservice@camber	08854		Group E-mail:		somaraju@he	eterousa.com		
Phone Number:	1-866-827-3647	·			Fax:	732-562-8788	priarrita.com	c Special rec	julations for product in any	states?			No	1
Product Therapeutic Classification		Synthetic nucleosid	le analogue antiviral					o. opoolai rog	Special returns requirement				No	1
Troduct Therapeutic Glassification	JII.	Cynanolic macrocolo	io unaloguo unavirui		J				Openiar returns requiremen	is for this product:			140	
	ADDITI	ONAL PRODUCT IN	FORMATION			PRODUCT DESCR	RIPTION INFORMATION	d. Store prod	uct (unit of sale) upright?				No	1
The product is?			Is the Product	Direct-Ship C	inly				Protect product (unit of sa	ula) from light?			No	i
a legend device?		No	Is the Product	Neither	'iiy		100 ct	e. Shelf life:	Protect product (unit of Sa	ile) iroin light?			24	Months
if yes, enter class #		140	Orphan Drug Status	110111101		Size:	100 01	c. Onen me.	Initial shelf life at launch (if different):				Months
a product kit?		No				a	400 mg	I.						,
if yes, list NDCs of			FDA Approval Status			Strength:	<u>o</u>			ORDER INFORM	MATION			
component parts						Dosage Form:	Tablet							
reverse numbered?		No				Dosage Form.			Unit of Sale		What is the		unit?	
co-licensed?		No	Allergens Present						x Bottle		1 Bottle of 1			
latex-free?		Yes				Product Shape:	Shield shaped, flat		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes					D'al		Ampule					V
correctional institution block? opioid?		No No				Product Color:	Pink		Glass Tube		Minimum o	raer quantity	/ ?	Yes
Cannabinoid?		No	Country of Origin	India			Debossed with 'J' on one side and		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for	140	country of origin	maia		Product Imprint:	'49' in triangle on the other side		Vial Liquid Multi		If Yes. how	many of whi	ich package i	type?
hospital scanning?	u 4000 101		Is this product covered u	inder the					Vial Powder Sql			Each		7,000
If Unit Dose, indicate NDC here:			Trade Agreements Act (TAA)?	No				Vial Powder Multi			Inner/Cartor	n/Pack	
			_						Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
											_			
					Au		thorized Generic, other		Pl	IARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB					section	on fields are not applicable	Rec. sell unit	to customer?		Rx billing u	nit to pharm	асу:	
II. Generic Equivalent to What Bra	and?:	Zovirax										Each		
								(Write-in, e.g.	. 1 Vial)			Gram		
		DRUG SUPPL	LY CHAIN SECURITY ACT	(DSCSA) INFOR	MATION							Milliliter		
Does supplier meet DSCSA defin	ition of manufactur	or?	Yes	_	GLN:	0331722498975			JTEA	I AND PACKING I	NEORMATIO	N		
Is product exempt from DSCSA?		U1 1	No	\dashv	JLIT.	0001122430310				TACKING I	ORINIATIO			
			110							Dimensi	(IIC	-4- \		
If yes, select exemption: Other exemption - Write in:					GCP:			1	Weight Lbs.	Dimens Depth	ons (US msn Width	nts.) Height	Volume (Cube)	Saleable # Pieces
Is product repackaged?			No		If yes was a	iginal product purchased		Item/Each:		1			T	
Is product sold by manufacturer's	s exclusive distribu	itor?	Yes	_	direct from m			item/Lacii.	0.18	1.8	1.8	4	12.96	1
Has FDA granted waiver/exception			No	7		 ce manufacturer for repa	ckaged product	Box/Carton/B	Sundle/					
If yes, attach documentation fro							.	Inner Pack:						
								Case:	4.9	11.4	7.75	5	441.75	24
		GTI	N AND HIBCC PRODUCT I	NFORMATION					4.5	11.4	7.70		441.75	2-7
								Pallet:						
11			HIBCC			N-14	Unit of Use GTIN-14							
Saleable Unit of Measure	S	aleable Quantity			003	31722777018							ED HOE ON	v
X Item/Each	s	aleable Quantity							COST INFORMATION			WHOLESAL		400
X Item/Each Box/Carton/Bundle/Inner Pack	s	1			202	31722777012			COST INFORMATION			WHOLESAL	EK USE ONL	
X Item/Each Box/Carton/Bundle/Inner Pack X Case	s				203	31722777012		Regular Cost				WHOLESAL	ER USE ONL	
X Item/Each Box/Carton/Bundle/Inner Pack	s	1			203	31722777012		Regular Cost		\$12.64	Vendor #:		ER USE ONL	
X Item/Each Box/Carton/Bundle/Inner Pack X Case	s	1			203	31722777012		Regular Cost Invoice Cost	(WAC) (\$)	\$12.64		#:	ER USE ONL	
X Item/Each Box/Carton/Bundle/Inner Pack X Case	s	1			203	31722777012				\$12.64	Vendor #: Whsl. Code	#:	ER USE ONL	
X Item/Each Box/Carton/Bundle/Inner Pack X Case	s	1			203	31722777012		Invoice Cost	(WAC) (\$)	\$12.64	Vendor #: Whsl. Code	#:	ER USE ONL	
X Item/Each Box/Carton/Bundle/Inner Pack X Case	s	1						Invoice Cost As of date:	(WAC) (\$) 4/15/2024	\$12.64	Vendor #: Whsl. Code	#:	ER USE ONL	
X Item/Each Box/Carton/Bundle/Inner Pack X Case	S	1		ATA SHEET (SD			RT, LABEL AND PHOTO OF F	Invoice Cost As of date:	(WAC) (\$) 4/15/2024	\$12.64	Vendor #: Whsl. Code	#:	ER USE ONL	



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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? 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 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?