

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014					Intro	duction Type:	P	ost Launch Change		Final Version			Date:	4/11	/2017
			PRODUCT INFORMAT	ION						SPECIAL HANDL	ING AND ST	ORAGE REQ	UIREMENTS	*	
Company Name:	Camber Pharmaceuti	cale				Applicati	on.	ANDA	a. Temperature – Indio	ata the USB temper	roturo rongo	for this prod	unt		
Application Number for ND			١-	203834		Арріїсиц	<u> </u>	711071		iture Range	rature range			en 20 and 25	5 C (68° – 77° F
		i iliAio io(k)(ilica actice)	<i>y</i> .	200001						=		- CONTROLLOG !		on to and to	70 (00 11 1
DUNS:	82-667-4775									emperature Range Re	equirement				-
Proprietary Name (If Applical		Name: Acyclovir	400MG/100CT						(w	rite in)					
Selling Unit NDC:	31722-777-01 NA		Individual Unit NDC:	31722-777-0			72277701	8							
UDI			CVX Code:			Code: NA			Is this pi	oduct to be shipped t	o customers o	on ice?		No	_
Description:	Pink, shield shaped to	ablet, flat faced, bevel edg	ed punches, debossed with '	l' on lower punch and '49' i	in triangle on	upper punch.			Is this pr	oduct to be shipped t	to customers of	on dry ice?		No	_
Active Ingredient(s):		Acyclovir							b. Contact for tempera	ature excursion que	stions:				
						Name:	,								
URL for Additional Product In							Number	732-529-0423							
Address:	1031 Centennial Avenue Address 2:						Group E-mail: somaraju@heterousa.com								
City:	Piscataway State: NJ Zip: 08854 Customer Service Email: customerservice@camberpharma.com														
Key Contact: Phone Number:	Customer Service 732-529-0430			Fax:	732-562-		berpharma.	COM	c. Special regulations for product in any states? Special regulations for product for this product?						
				rax.	132-302	-0/00			Special returns requirements for this product? No						
Product Therapeutic Classifi	ication:														
			1						d. Store product (unit					No	_
ADDITIONA	AL PRODUCT INFORM	IATION			PRODUCT	DESCRIPTION	NINFORMA	ATION	Protect	product (unit of sale	e) from light?			No	=
Is the Product					_				e. Shelf life:					24	Months
a legend device?		No		Size:		100			Initial sh	nelf life at launch (if	different):				Months
reverse numbered?		No		3126.											
co-licensed?		No		Strength:		400 mg				(order infoi	RMATION			
Is the Product		Direct-Ship Only		Ou engui.		400 Hig									
Is the Product		Unit of Use		Dosage Forn	m:	Oral Solid Table	ets		Unit of S				NDC selling	unit?	
									J <u> </u>	Bottle		1 box of 24			
If Unit Dose, is item bar code	ed to unit dose for hose	ital scanning?			-				x	Box/Carton		(Write-in, e	.g. 1 Box of 1	0 Vials)	
11		, , , , , , , , , , , , , , , , , , ,		Product Sha	pe:	Shield shaped				Ampule					
If Unit Dose NDC, indicate NI	DC here:				·					Glass		Minimum o	rder quantity	/?	Yes
		I. P.		Product Cold	or:	Pink				Tube					
Country of Origin		India			-					Vial Liquid Sgl		W. W			
Is this product covered under the Trade Agreements Act (TAA)?						Vial Liquid Multi Vial Powder Sql		if Yes, now	Each	ch package	type?				
		No No			L				' 	Vial Powder Sqi Vial Power Multi		24	Inner/Cartor	/Dack	
			1							Other: Write In		24	Case	VI ack	
			FOR GENERIC DRUG PRO	DUCTS						Other. Write in			Case		
											_				
				Auth	horized Gene	eric *If A	Authorized (Generic, other section		PHAF	RMACY ORDE	R / BILL UN	T		
fields are not applicable															
I. Orange Book Rating:		Zovirax													
II. Generic Equivalent to What Brand?: Zovirax				(Write-in, e.g. 1 Vial)	(Write-in, e.q. 1 Vial) Each										
		DRUG SUPPI	LY CHAIN SECURITY ACT (E	SCSA) INFORMATION					(vviite iii, e.g. 1 viai)			-	Milliliter		
				· · · · · · · · · · · · · · · · · · ·											
Does supplier meet DSCSA	definition of manufac	turer?	Yes	GLN:						ITEM A	AND PACKING	INFORMAT	ON		
Is product exempt from DSC			No												
If yes, select exemption:										Weight Lbs.	Dime	nsions (US n	ismts.)	Volume	# Pieces:
Other exemption - Write in:	:									weight Lbs.	Depth	Height	Width	(Cube)	# Fleces.
Is product repackaged?			No	If Yes, was origin	nal product	purchased di	rect		Item:	0.2		4	1.8		
Is product sold by manufact			No	from mfr?			_		· L	0.2		4	1.0		
Has FDA granted waiver/exc	eption/exemption for	product?	No	If yes, attach do	cumentation	n from FDA.			Box/Carton/Bundle/						
									Inner Pack:						
			GTIN PRODUCT INFORM						Case:	4.9	12	5	8	0.277	24
11				aleable			·					Ŭ	Ü	V.L	
			Level	Unit				STIN-14	Pallet:						2688
Serialized?	Yes	x	Item	x 2D		Linear	1 0	0331722777018							
If not, when?			Box/Carton/Bundle/Inner Pack	2D		Linear			UPC:	Case:					
Items aggregated?	Yes	х	Case	x x 2D			4 2	0331722777012		Carton:					
11			Pallet	2D		Linear									
11				2D		Linear			COST	INFORMATION			WHOLESAL	ER USE ON	LY:
[]				2D		Linear						l			
				2D		Linear			Regular Cost			Vendor #:			
11				2D		Linear			Invoice Cost (WAC) (\$		\$18.50				
[L									Federal Excise Tax Pe	r Unit of Sale		Fineline Co	de:		
									As of date:			4			
												l			
1			Attach copy of SAFETY DA	TA SHEET (SDS) or non h					ODUCT PACKAGING and BA						
	nal information on page	70.2			Con now	p. 3 for Design	mated Dre	n Chin Only	Signatu	ro.					



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL H	HAZARD CLASSIFICATION and TRANSPORTATION	
Is this product (check all that apply):		,
a. Cytotoxic?	SDS Hazard Classification	
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	ODO HAZARA GRADANIONI	
Is the product a CA Prop 65 carcinogen?	Organic Corrosive	
Is the product a CA Prop 65 carcinogen?	Inorganic Oxidizer	
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard	
- O-st-st-H10	Associated Characteristic NETPA Characteristics	
c. Contact Hazard?	Aerosol Class; Identify NFPA Storage Level:	
d. Does this product require special clean-up instructions? No		
(If yes, attach SDS with special instructions.)	Is the product a NIOSH hazardous drug?	
e. Does the product contain DEHP?	If yes, indicate which:	
Is this product regulated for shipment by DOT or IATA?		
(if yes, answer a-e below and provide SDS)		
a. UN/Identification Number		
b. Proper Shipping Name	Hazardous Waste Identification	
c. DOT Hazard Class	EPA Hazardous Waste Code:	
d. Packing Group		
e. Inhalation Hazard?		
	DELIA DEGLETA DESTRUCTIONA	
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS	
Passenger	Is there a REMS on this product?	
Cargo	If Yes, is it managed with a pharmacy registry?	
Passenger & Cargo	Website URL:	
Is this a reportable quantity? No		
RQ Threshold:	Comments / Details: (For example, iPledge program?)	
Is this a marine pollutant?		
Is this product shipped utilizing an authorized DOT exception or Special Permit?		
No (if yes, identify method below)	REMS:	
Limited Quantity	REMS Program Manager Name: Phone:	
Consumer Commodity, ORM-D	Supplier Manages REMS registry exclusively: No	
Small Quantity (49 CFR 173.4)	Wholesale distributor support: No	
Special Permit; DOT-SP	Provider Name:	
Special Provision (listed in Column 7 of 49 CFR 172.101);	Site Enrollment Number assigned DEA #: No	
SP#	by Supplier: PCPDP #: No	
01 #		
ADD'L STORAGE INFORMATION	NPI #: No	
Is the Product	Comments	
	Comments	
	Pariety, No.	
Controlled by State(s)? ARCOS Reportable? No	Registry: No	
·	Registry Program Contact Name: Phone:	
Schedule No. (inc. N for non-narcotic)	Comments	
Controlled Substance Code	RETURN INSTRUCTIONS	
Listed Chemical (List I or II) No	RETURN INSTRUCTIONS	
If yes, indicate which:		
Is it a scheduled listed chemical product?: No	Contact tel. # if product received damaged: 732-529-0430	
CLASS OF TRADE RESTRICTION:	Is product returnable for credit:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	URL/Link to returns policy: contact - customerservice@camberpharma.com	
Restricted to retail pharmacy only: Yes	Special regulations or returns requirements for this product in certain states?	
Restricted to hospital, clinics, and physician offices only:	If so, which states? Other requirements? Comments?	
Restricted from US territories? (explain in comments) No		
Comments:		
Comments.		
MISCELLAN	NEOUS NOTES and/or Image of Product Barcode:	



Standard Pharmaceutical Product Information (Page 3)

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 Yes No Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time: 2:30PM Eastern					
c. Fax d. Phone only No Phone No.:	Shipping lead time of PO: 24/48 Hours Days					
e. Supplier Web Site only No Site Address:	Ships same day for next day receipt: No					
Minimum Order Quantity: case pack	Ships for second day receipt: No					
Supplier's Customer Service Number: 732-529-0430 x466 x465 x467 x470	Ships regular ground for 3-10 days receipt: Yes					
Contracted 3PL company / contact #: Name: Phone:						
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing					
Expedited freight fees billed with each order: No No	Overnight receipt available: Yes					
Drop Ship service fee billed with each order: No No	PO Receipt cut off time: 2:30PM Eastern					
Drop Ship miscellaneous fees billed: No	Days of week overnight is available:					
Comments:	x Tuesday x Wednesday Thursday x Friday					
	Priority Overnight receipt available: Yes					
Class of Trade Restriction:	PO Receipt Cut off time: 2:30PM EST					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No	Saturday Overnight receipt available: No					
Restricted to retail pharmacy only: Yes	PO Receipt Cut off time:					
Restricted to hospital, clinics, and physician offices only: No	Order receipt method: No Phone #:					
Restricted from US territories? (explain in comments) No	Fax: Yes Fax #: 732-562-8788					
Comments:	EDI: Yes					
	Overnight Fees apply: Other fees apply: No					
Other Data Information Demoired to Decree DO						
Other Data Information Required to Process PO:	Return Instructions					
Patient Procedure Date: Physician Name:	Contact # if product is received damaged: Is product returnable for credit: Yes					
Physician/Clinic Phone #	URL/Link to returns policy:					
Physician State License #	Special regulations or returns requirements for this product in certain states? Yes					
Physician/Clinic DEA #:	If so, which states? Other requirements? Comments?					
Physician/Clinic Specialty:	·					
Miscellaneous Notes:						
	ADDITIONAL INFORMATION					
	Is product order for scheduled patient procedure?					
	Is product order for restocking purposes?					