

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014						Introduction	Туре:	Pos	t Launch Change		Final Version			Date:		
			PRODUCT INFORMA	ATION							SPECIAL HANDL	ING AND ST	ORAGE REQ	UIREMENTS		
Company Name:	Camber Pharmaceuti	cals				Ap	plication:		ANDA	a. Temperature - Indic	ate the USP temper	ature range	for this prod	uct.		
Application Number for ND	A/ANDA/BLA (drug);	PMA/510(k)(med devic	e):	2038	34	•		•			ture Range	•			en 20 and 25	C (68° – 77° I
DUNS:	82-677-4775									Other Te	mperature Range Re	quirement				
Proprietary Name (If Applica	ble) and Established	Name: Acyclov	rir 800MG/100CT							(wi	ite in)					
Selling Unit NDC:	31722-778-01		Individual Unit NDC:	: 3	1722-778-01	UPC:	3317227	778015								
UDI	NA		CVX Code:			MVX Code:	NA			Is this pr	oduct to be shipped to	customers of	on ice?		No	_
Description:	Blue, oval shaped tab	olet, flat faced compound	cup punches, debossed with	h 'J' on lower pur	nch and '50' in	triangle on upper p	unch.			Is this pr	oduct to be shipped to	customers of	on dry ice?		No	_
Active Ingredient(s):		Anualauia														
Active ingredient(s):		Acyclovir								b. Contact for tempera Name:	iture excursion que	stions:	Soma Raju			
URL for Additional Product I	nformation:	www.camberpharma.co	m							Number	:		732-529-04	23		
Address:	1031 Centennial Avenue			Address 2:			Group E	-mail:		somaraju@h	neterousa.co	n				
City:	Piscataway State: NJ Zip: 08854 Customer Service Email: customerservice@camberoharma.com															
Key Contact: Phone Number:	Customer Service 732-529-0430				Email: customerservice@camberpharma.com Fax: 732-562-8788			c. Special regulations			**2		No No	=		
Product Therapeutic Classifi								Special returns requirements for this product? No								
Troudet merapeatic olassiii	ioution.									d. Store product (unit	of sale) unright?				No	
ADDITIONA	AL PRODUCT INFORM	IATION			Р	RODUCT DESCR	IPTION INF	ORMATI	ION		product (unit of sale) from light?			No	_
Is the Product			7							e. Shelf life:		-			24	Months
a legend device?		No			ize:	100				11	elf life at launch (if o	different):				Months
reverse numbered?		No	_	"	126.	100										_'
co-licensed?	No No			s	trength:	800 mg				ORDER INFORMATION						
Is the Product		Direct-Ship Only Unit of Use	•							Unit of S	Salo		What is the	NDC selling	unit?	
is the rioduct		0.11. 0.1 0.00		D	osage Form:	Oral Soli	d tablet			One or o	Bottle		1 box of 12		<u></u>	
If Unit Dose, is item bar code	nd to unit dose for hose	ital scanning?								х	Box/Carton		(Write-in, e	.g. 1 Box of 1	0 Vials)	
	·	itai scaiiiiig:		P	roduct Shape	e: Oval					Ampule				_	
If Unit Dose NDC, indicate N	DC here:		i								Glass Tube		Minimum o	rder quantity	?	Yes
Country of Origin		India	1	P	roduct Color:	Blue					Vial Liquid Sgl					
]	r the Trade Agreements	Act (TAA)2	·		roduct Imprin	J'/50'				Vial Liquid Multi If Yes, how many of which package type?						
Is this product covered under the Trade Agreements Act (TAA)? No Product Imprint:				0730	3730			Vial Powder Sql Each								
										<u> </u>	Vial Power Multi Other: Write In		12	Inner/Cartor Case	/Pack	
			FOR GENERIC DRUG PI	RODUCTS							Other: write in	1	12	Case		
												_				
					Author	rized Generic			neric, other section		PHAR	MACY ORDE	ER / BILL UN	T		
I. Orange Book Rating: AB fields are not applicable						olicable	Rec. sell unit to customer? Rx billing unit to pharmacy:				асу:					
II. Generic Equivalent to What Brand?: Zovirax					Each											
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							(Write-in, e.g. 1 Vial) Gram Milliliter									
		5,100 001	,21 012 02001 1 7101	(2000), 0.										Williame		
Does supplier meet DSCSA		turer?	Yes	GLN:							ITEM A	ND PACKING	INFORMATI	ION		
Is product exempt from DSC	SA?		No	_												
If yes, select exemption:											Weight Lbs.		nsions (US m		Volume (Cube)	# Pieces:
Other exemption - Write in: Is product repackaged?	•		No	If Yes	s. was original	I product purchas	sed direct			Item:		Depth	Height	Width	(Cube)	
Is product sold by manufact	urer's exclusive distr	ibutor?	No	from		, p					0.3		4.5	2.75		
Has FDA granted waiver/exc	eption/exemption for	product?	No	If yes	, attach docu	mentation from F	DA.			Box/Carton/Bundle/						
			GTIN PRODUCT INFOR	DMATION						Inner Pack:					<u> </u>	
			GTIN PRODUCT INFOR	Saleable						Case:	4.5	10	6	8.75	0.303	12
			Level	Unit			Quantity	/ GTI	N-14	Pallet:						1296
Serialized?	Yes	х	Item		x 2D	Linear	1	003	331722778015							1296
If not, when?			Box/Carton/Bundle/Inner Pack		2D	Linear				UPC:	Case:					
Items aggregated?	Yes	x	Case	x	X 2D 2D	Linear	12	203	331722778019		Carton:					
			railet	+ + +	2D 2D	Linear				COST	INFORMATION			WHOLESAL	LER USE ONL	LY:
					2D	Linear										
					2D	Linear				Regular Cost			Vendor #:			
					2D	Linear				Invoice Cost (WAC) (\$		\$30.25				
										Federal Excise Tax Pe As of date:	r unit of Sale	1	Fineline Co	ae:		
										7.5 of date.						
			Attach copy of SAFETY [DATA SHEET (SE	OS) or non haz	ard letter, PACKAG	SE INSERT	, LABEL	AND PHOTO OF PRO	ODUCT PACKAGING and BA	ARCODE.		•			
*Please provide any addition	nal information on page	qe 2.		(02	,	See new p. 3 for				Signatu						



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL I	HAZARD CLASSIFICATION and TRANSPORTATION							
Is this product (check all that apply): a. Cvtotoxic? No	SDS Hazard Classification							
	SDS HAZAFU CIASSILICATION							
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?								
Is the product a CA Prop 65 carcinogen? No	Organic Corrosive							
Is the product a CA Prop 65 reproductive toxicant?	Inorganic Oxidizer							
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard							
	_							
c. Contact Hazard?	Aerosol Class; Identify NFPA Storage Level:							
d. Does this product require special clean-up instructions?								
(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? No								
(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: N/A							
d. Packing Group								
e. Inhalation Hazard?								
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? No								
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							
	NPI #: No							
ADD'L STORAGE INFORMATION								
Is the Product	Comments							
Controlled Substance? No								
Controlled by State(s)?	Registry: No							
ARCOS Reportable? No	Registry Program Contact Name: Phone:							
Schedule No. (inc. N for non-narcotic)	Comments							
Controlled Substance Code								
Listed Chemical (List I or II)	RETURN INSTRUCTIONS							
If yes, indicate which:								
Is it a scheduled listed chemical product?:	Contact tel. # if product received damaged: 732-529-0430							
CLASS OF TRADE RESTRICTION:								
CLASS OF TRADE RESTRICTION:	Is product returnable for credit: Yes							
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: No	If so, which states? Other requirements? Comments?							
Restricted from US territories? (explain in comments) No								
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?						