

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014 Introduction Type: Post Launch Change Final Version Date: 5/2/2017															
			PRODUCT INFORMATI	ON						SPECIAL HANDL	ING AND STO	RAGE REQ	UIREMENTS	*	
Company Name:	Camber Pharmaceuti	cale				Application:		ANDA	a. Temperature – Indic	ata the USB temper	oturo rongo i	or this produ	unt		
Application Number for ND				203047		Application.		711071		ture Range	ature range i			en 20 and 25	5 C (68° – 77° F
		miros ro(k)(med device)	-	2000 11					-	=		0011110110411			70 (00 11 1
DUNS:	82-667-4775									mperature Range Re	quirement				7
Proprietary Name (If Applical		Name: Valacyclo	ovir Hydrochloride Tablets 500						(wr	ite in)					
Selling Unit NDC:	31722-704-90		Individual Unit NDC:	31722-704-90			2704908								
UDI			CVX Code:		MVX Co	de:			Is this pr	oduct to be shipped to	customers o	n ice?		No	_
Description:	Blue, capsule shaped	tablets embossed with 'I'	on lower punch and '86' on up	per					Is this pr	oduct to be shipped to	customers o	n dry ice?		No	_
Active Ingredient(s):		Valacyclovir Hydrochloric	de						b. Contact for tempera	ture excursion que	stions:				
						Name:			Soma Raju						
	Additional Product Information: www.camberpharma.com					Number		732-529-0423							
Address:	1031 Centennial Avenue Address 2:						Group E-mail: somaraju@heterousa.com								
City:	Piscataway			State:	NJ	Zip:		854			0				
Key Contact: Phone Number:	Customer Service Email: customerservice@camberpharma.com				UIII	c. Special regulations for product in any states? Special returns requirements for this product? No									
Product Therapeutic Classifi		Fax: 732-562-8788					Special returns requirements for this product?								
Product Therapeutic Classifi	ication:														
ADDITIONA	AL PRODUCT INFORM	ATION	Ī		PRODUCT DE	CCDIDTION IN	CODMAT	TION	d. Store product (unit		\			No No	_
	AL PRODUCT INFORM	ATION			PRODUCT DE	SCRIPTION IN	FURIMA	ION	Protect product (unit of sale) from light? No					=	
Is the Product									e. Shelf life: 24			24	Months		
a legend device?		No		Size:	90				Initial sh	elf life at launch (if o	different):				Months
reverse numbered?		No									NADED INFO	MATION			
co-licensed?		Direct-Ship Only		Strength:	500	mg				•	ORDER INFO	RMATION			
Is the Product Is the Product		Unit of Use							Unit of S	-l-		What is the	NDC selling		
is the Froduct		Offit of Ose		Dosage Form	: Oral	l solid tablet			Offic of 3	Bottle		I box of 24 b		, unit:	
									x	Box/Carton			g. 1 Box of 1	0 Vials)	
If Unit Dose, is item bar code	ed to unit dose for hosp	ital scanning?								Ampule		(**************************************	.g Dox or .	o viaio,	
If Unit Dose NDC, indicate NI	DC here:			Product Shap	caps	sule shaped				Glass		Minimum o	rder quantity	/?	Yes
				Product Color	r: blue					Tube					
Country of Origin		India		Product Color	r: blue	•				Vial Liquid Sgl					
le this product covered under	r the Trade Agreements	Act (TAA)2		Product Impri	int: 1'/'86	8'			Vial Liquid Multi If Yes, how many of which package type?						
Is this product covered under the Trade Agreements Act (TAA)? No Product Imprint:			1700	Vial Powder Sql					Each						
									<u> </u>	Vial Power Multi		24	Inner/Cartor	√Pack	
									_	Other: Write In	-		Case		
			FOR GENERIC DRUG PRO	DUCTS							_				
						*16 * 11				DUAD	MACY ORDE	D / DILL LINI	-		
				Autno	orized Generic		re not ap	eneric, other section			IWACTORDE				
I. Orange Book Rating:	AB	L				ileius a	ie not ap	plicable	Rec. sell unit to customer? Rx billing unit to pharmacy:						
II. Generic Equivalent to What Brand?: Valtrex				Each											
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION						(Write-in, e.g. 1 Vial) Gram									
		DRUG SUFFI	T CHAIN SECORITT ACT (D	SCSA) INFORMATION									Milliliter		
Does supplier meet DSCSA	definition of manufac	turor?	Yes	GLN:						ITEM A	ND PACKING	INFORMATI	ON		
Is product exempt from DSC			No	OLIV.									···		
If yes, select exemption:											Dimer	sions (US m	smts.)	Volume	
Other exemption - Write in:	:									Weight Lbs.	Depth	Height	Width	(Cube)	# Pieces:
Is product repackaged?			No	If Yes, was origina	al product pur	chased direct			Item:	0.2		4.25	2		
Is product sold by manufact			No	from mfr?						0.2		4.20			
Has FDA granted waiver/exc	eption/exemption for	product?	No	If yes, attach doc	umentation fro	om FDA.			Box/Carton/Bundle/						
									Inner Pack:						
			GTIN PRODUCT INFORMA						Case:	5.75	11.75	5.5	8	0.299	24
[]				aleable											
			_	Unit		Quantit		ΠN-14	Pallet:						2688
Serialized?	Yes		Item	x 2D	Line		00	331722704908	LIBO			L	<u> </u>		
If not, when?	Vee		Box/Carton/Bundle/Inner Pack	2D	Line		20	224722704002	UPC:	Case:					
Items aggregated?	Yes	_ x	Case Pallet	x x 2D 2D	Line		20	331722704902		Carton:					
[]			i anot	2D 2D	Line		1 –		_cost	INFORMATION	_		WHOLESAL	LER USE ON	LY:
11				2D 2D	Line		1			Oranization			O-ELEO/AL	LIN GOL ON	
11				2D	Line		1 📙		Regular Cost			Vendor #:			
[]	2D				Linear			Invoice Cost (WAC) (\$)	\$73.29	Whsl. Code	#:			
									Federal Excise Tax Pe		,	Fineline Co			
									As of date:						
			Attach copy of SAFETY DAT	A SHEET (SDS) or non ha	zard letter, PAC	CKAGE INSER	T, LABEL	AND PHOTO OF PR	ODUCT PACKAGING and BA	RCODE.					
*Diagon manuido anu addition	nal information on pag	ıe 2	* *			3 for Designat			Signatur						



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. Cytotoxic?	SDS Hazard Classification	
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	ODO HAZARA GIAGGIRIGATORI	
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	
a Contact Haranda	A arread Class Identify NEDA Ctarage Levels	
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? 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: NA	
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:	
	Website ORL.	
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 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)
<u></u>	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) 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:	
N c c		
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No	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? No	
Restricted to hospital, clinics, and physician offices only:	If so, which states? Other requirements? Comments?	
Restricted from US territories? (explain in comments) No		
Comments:		
MISCELLAI	ANEOUS 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?					