

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014					Introduction Type:	Post Launch Change		Final Version			Date:	5/2/	/2017
			PRODUCT INFORMATION					SPECIAL HANDL	ING AND STO	DRAGE REQ	JIREMENTS'	*	
Company Name:	Camber Pharmaceuti	cale			Application:	ANDA	a. Temperature – Indic	ata the USB temper	oturo rongo i	ior thio prod	ıot		
Application Number for ND				203047	Арріісаціон.	744574		ture Range	ature range i			en 20 and 25	5 C (68° – 77° F
		miros ro(k)(med device)	•	2000			-	=		0011110110411	oom boure	011 20 4114 20	70 (00 11 1
DUNS:	82-667-4775							mperature Range Re	quirement				7
Proprietary Name (If Applical		Name: Valacyclo	ovir Hydrochloride Tablets 1000MG				- (wr	ite in)					
Selling Unit NDC:	31722-705-30		Individual Unit NDC:	31722-705-30		2705301							
UDI			CVX Code:		MVX Code:		Is this pr	oduct to be shipped to	o customers c	in ice?		No	_
Description:	White to off-white cap	sule shaped tablets embo	ssed with 'I' on lower punch and '8	7' on upper			Is this pr	oduct to be shipped to	o customers o	n dry ice?		No	_
Active Ingredient(s):		Valacyclovir Hydrochloric	de				b. Contact for tempera	ture excursion que	stions:				
							Name:			Soma Raju			
URL for Additional Product In					Number: 732-529-0423 Group E-mail: somaraju@heterousa.com								
Address:	1031 Centennial Ave	nue					Group E	-mail:		somaraju@r	eterousa.cor	n	
City:	Piscataway Customer Service			State: NJ Email: cusi	Zip: stomerservice@camberp	08854						No	
Key Contact: Phone Number:	732-529-0430				2-562-8788	onarma.com	c. Special regulations	ror product in any s eturns requirements f				No	_
		1		Fax. [732	2-302-0700		Special i	eturns requirements i	ior this produc	il?		INO	_
Product Therapeutic Classifi	ication:												
		A THE A L	•				d. Store product (unit					No	_
ADDITIONA	AL PRODUCT INFORM	ATION		PROD	DUCT DESCRIPTION IN	FORMATION	Protect	product (unit of sale	e) from light?			No	=
Is the Product							e. Shelf life:					24	Months
a legend device?		No		Size:	30		Initial sh	elf life at launch (if o	different):				Months
reverse numbered?		No		OLC.	30								
co-licensed?		No		Strength:	1000 mg			C	ORDER INFO	RMATION			
Is the Product		Direct-Ship Only		oorigani	- coo mg								
Is the Product		Unit of Use		Dosage Form:	Oral solid tablet		Unit of S				NDC selling	unit?	
				-			<u> </u>	Bottle		1 box of 24		0.15-1-1	
If Unit Dose, is item bar code	ed to unit dose for hosp	ital scanning?					х	Box/Carton		(write-in, e.	g. 1 Box of 1	u viais)	
If Unit Dose NDC, indicate NI	DC horo:			Product Shape:	capsule shaped			Ampule Glass		Minimum o	der quantity		Yes
II Unit Dose NDC, Indicate No	DC nere:							Tube		winimum o	der quantity	1	res
Country of Origin		India		Product Color:	white			Vial Liquid Sgl					
								Vial Liquid Multi		If Yes, how	manv of whi	ch package	type?
Is this product covered under	r the Trade Agreements	Act (TAA)?		Product Imprint:	I'/'87'			Vial Powder Sql			Each		71
								Vial Power Multi			Inner/Carton	/Pack	
			•				-	Other: Write In		24	Case		
			FOR GENERIC DRUG PRODUC	TS									
				10					_				
				<u> </u>									
				Authorized		orized Generic, other section		PHAR	RMACY ORDE	R / BILL UNI	Т		
I. Orange Book Rating:	AB			<u> </u>		orized Generic, other section re not applicable	Rec. sell unit to custor		RMACY ORDE		T nit to pharm	асу:	
I. Orange Book Rating: II. Generic Equivalent to Wha		Valtrex		<u> </u>					RMACY ORDE		nit to pharm	асу:	
				Authorized			Rec. sell unit to custor (Write-in, e.g. 1 Vial)		RMACY ORDE		nit to pharm Each Gram	асу:	
			Y CHAIN SECURITY ACT (DSCS.	Authorized					RMACY ORDE		nit to pharm	асу:	
II. Generic Equivalent to Wha	at Brand?:	DRUG SUPPL	•	Authorized A) INFORMATION				ner?		Rx billing u	nit to pharm Each Gram Milliliter	асу:	
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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?				