

## **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	RAGE REQ	UIREMENTS	*	
Company Name:	Camber Pharmaceuti	cale			Application	n: ANDA	a. Temperature – Indio	ata the UCD tamper	oturo rongo i	or this prod	uot		
Application Number for ND			1	203047	Application	7,467		iture Range	ature range i			en 20 and 25	C (68° – 77° F
		mayoro(k)(mea aevice)	•	2000 11			<b>-</b>	=		- COTTLI CHICA T	toom bottee	011 20 4114 20	
DUNS:	82-667-4775							emperature Range Re	quirement				-
Proprietary Name (If Applical		Name: Valacyclo	ovir Hydrochloride Tablets 500MG				(wi	rite in)					
Selling Unit NDC:	31722-704-30		Individual Unit NDC:	31722-704-30		22704304	<b>-  </b>						
UDI			CVX Code:		MVX Code:		Is this pr	oduct to be shipped to	o customers c	n ice?		No	_
Description:	Blue, capsule shaped	tablets embossed with 'I'	on lower punch and '86' on upper				Is this pr	oduct to be shipped to	o customers o	n dry ice?		No	_
Active Ingredient(s):		Valacyclovir Hydrochlori	de				b. Contact for tempera	ature excursion que	stions:				
							Name:			Soma Raju			
URL for Additional Product In	ict Information: www.camberpharma.com  1031 Centennial Avenue Address 2:				Number: 732-529-0423 Group E-mail: somaraju@heterousa.com								
Address:		nue				Inner i	Group E	-mail:		somaraju@r	neterousa.co	n	
City:	Piscataway         State:         NJ         Zip:         08854           Customer Serivce         Email:         customerservice@camberpharma.com										N1.		
Key Contact: Phone Number:	732-529-0430		Email: customerservice@camberpharma.com Fax: 732-562-8788			c. Special regulations for product in any states?  Special returns requirements for this product?  No				-			
Product Therapeutic Classifi					32-302-0700			returns requirements i	ioi tilis produc	t:		140	-
Product Therapeutic Classifi	ication:												
A DDITIONA	AL PRODUCT INFORM	ATION	Ī	DD.	DDUCT DESCRIPTION II	NEORMATION	d. Store product (unit	of sale) upright? product (unit of sale				No No	_
	AL PRODUCT INFORM	ATION		FRO	DOUCT DESCRIPTION II	NFORWATION		product (unit of sale	e) from light?				=
Is the Product							e. Shelf life:					24	Months
a legend device?		No		Size:	30		Initial sh	nelf life at launch (if o	different):				Months
reverse numbered?		No								MATION			
co-licensed?		No No		Strength:	500 mg			•	ORDER INFO	RMATION			
Is the Product Is the Product		Direct-Ship Only Unit of Use					Unit of S	Sala.		What is the	NDC selling	unit?	
is the Froduct		Offit of Ose		Dosage Form:	Oral solid tablet		Onit of S	Bottle		1 box of 24		unit:	
							1 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?					ı   <del>  ^</del>	Ampule		(**************************************	.g Dox o	o vidio)	
If Unit Dose NDC, indicate NI	DC here:			Product Shape:	capsule shaped			Glass		Minimum o	rder quantity	1?	Yes
				Product Color:	blue			Tube					-
Country of Origin		India		Product Color:	blue			Vial Liquid Sgl					
Is this product covered under	r the Trade Agreements	Act (TAA)2		Product Imprint:	1'/'86'			Vial Liquid Multi		If Yes, how	many of whi	ch package	type?
is this product covered under	i tile Trade Agreements	No No		1 Todact implint.	17 00			Vial Powder Sql			Each		
							<b>」</b> ┃	Vial Power Multi			Inner/Cartor	/Pack	
											Case		
								Other: Write In	-	24	Jouos		
			FOR GENERIC DRUG PRODUC	TS				Other: Write In		24	10000		
			FOR GENERIC DRUG PRODUC	<u> </u>	*10	Lain 10 and all and a			RMACY ORDE				
			FOR GENERIC DRUG PRODUC	<u> </u>		horized Generic, other section		PHAR	RMACY ORDE	R / BILL UNI	IT		
I. Orange Book Rating:	AB	To a control of the c	FOR GENERIC DRUG PRODUC	<u> </u>		horized Generic, other section are not applicable	Rec. sell unit to custo	PHAR	RMACY ORDE	R / BILL UNI	T nit to pharm	асу:	
I. Orange Book Rating:		Valtrex	FOR GENERIC DRUG PRODUC	<u> </u>				PHAR	RMACY ORDE	R / BILL UNI	nit to pharm	асу:	
				Authorize			Rec. sell unit to custo (Write-in, e.g. 1 Vial)	PHAR	RMACY ORDE	R / BILL UNI	nit to pharm Each Gram	асу:	
			FOR GENERIC DRUG PRODUC	Authorize				PHAR	RMACY ORDE	R / BILL UNI	nit to pharm	асу:	
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## **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?				