



# Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:  Post Launch Change

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	Camber Pharmaceuticals
Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	205166
DUNS:	82-667-4775
Proprietary Name (If Applicable) and Established Name:	Valganciclovir Tablets 450MG 60CT
Selling Unit NDC:	31722-832-60
Individual Unit NDC:	31722-832-60
UPC:	331722832601
UDI	
CVX Code:	
MVX Code:	
Description:	Pink oval-shaped tablets embossed with '156' on upper punch and 'J' on lower
Active Ingredient(s):	Valganciclovir
URL for Additional Product Information:	www.camberpharma.com
Address:	1031 Centennial Avenue
City:	Piscataway
Key Contact:	Customer Service
Phone Number:	732-529-0430
State:	NJ
Address 2:	
Zip:	08854
Email:	customerservice@camberpharma.com
Fax:	732-562-8788
Product Therapeutic Classification:	

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
Temperature Range	Controlled Room – between 20 and 25 C (68° – 77° F)
Other Temperature Range Requirement (write in)	
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No
b. Contact for temperature excursion questions:	
Name:	Soma Raju
Number:	732-529-0423
Group E-mail:	somaraju@heterousa.com
c. Special regulations for product in any states?	No
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	No
Protect product (unit of sale) from light?	No
e. Shelf life:	
Initial shelf life at launch (if different):	<input type="text" value="24"/> Months

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device?	No
reverse numbered?	No
co-licensed?	No
Is the Product... Direct-Ship Only	
Is the Product... Unit of Use	
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input checked="" type="checkbox"/>
If Unit Dose NDC, indicate NDC here:	
Country of Origin	India
Is this product covered under the Trade Agreements Act (TAA)?	No

PRODUCT DESCRIPTION INFORMATION	
Size:	60
Strength:	450 mg
Dosage Form:	Oral solid tablet
Product Shape:	oval
Product Color:	pink
Product Imprint:	156/'J'

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input type="checkbox"/> Bottle	<input type="text" value="1 box of 24 bottles"/>
<input checked="" type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity? Yes
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	If Yes, how many of which package type?
<input type="checkbox"/> Vial Liquid Multi	<input type="text" value="24"/> Each
<input type="checkbox"/> Vial Powder Sgl	<input type="text" value=""/> Inner/ Carton/ Pack
<input type="checkbox"/> Vial Power Multi	<input type="text" value=""/> Case
<input type="checkbox"/> Other: Write In	

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	Valcyte
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="text" value="1 Vial"/>	<input type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	No
Is product sold by manufacturer's exclusive distributor?	No
Has FDA granted waiver/exception/exemption for product?	No
GLN:	
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Box/Carton/Bundle/Inner Pack:	0.15		3.5	1.5		
Case:	4.15	11	4.5	8	0.229	24
Pallet:						1968
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION						
Serialized?	Level	Saleable Unit	Quantity	GTIN-14		
				Item	Case	Pallet
<input checked="" type="checkbox"/>	Box/Carton/Bundle/Inner Pack		1	00331722832601		
<input checked="" type="checkbox"/>	Case		24	20331722832605		
<input checked="" type="checkbox"/>	Pallet					

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$300.00	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:			

**For Designated Drop Ship Only Products, Please Use Page 3**  
**MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION**

Is this product (check all that apply):

a. Cytotoxic? No

b. CA Prop. 65 Carcinogen or Reproductive Toxicant?  
 Is the product a CA Prop 65 carcinogen? No  
 Is the product a CA Prop 65 reproductive toxicant? \_\_\_\_\_  
 Does the product label bear a CA Prop 65 warning? \_\_\_\_\_

c. Contact Hazard? No

d. Does this product require special clean-up instructions?  
 (If yes, attach SDS with special instructions.) No

e. Does the product contain DEHP? No

Is this product regulated for shipment by DOT or IATA?  
 (if yes, answer a-e below and provide SDS) No

a. UN/Identification Number \_\_\_\_\_

b. Proper Shipping Name \_\_\_\_\_

c. DOT Hazard Class \_\_\_\_\_

d. Packing Group \_\_\_\_\_

e. Inhalation Hazard? \_\_\_\_\_

Is the product restricted for air shipment? If so, indicate restriction:

Passenger

Cargo

Passenger & Cargo

Is this a reportable quantity? No  
 RQ Threshold: \_\_\_\_\_

Is this a marine pollutant? No

Is this product shipped utilizing an authorized DOT exception or Special Permit?  
 No (if yes, identify method below)

Limited Quantity

Consumer Commodity, ORM-D

Small Quantity (49 CFR 173.4)

Special Permit; DOT-SP

Special Provision (listed in Column 7 of 49 CFR 172.101);  
 SP# \_\_\_\_\_

**ADD'L STORAGE INFORMATION**

Is the Product...

Controlled Substance? No

Controlled by State(s)? No

ARCOS Reportable? No

Schedule No. (inc. N for non-narcotic) \_\_\_\_\_

Controlled Substance Code \_\_\_\_\_

Listed Chemical (List I or II) No

If yes, indicate which: \_\_\_\_\_

Is it a scheduled listed chemical product?: No

**CLASS OF TRADE RESTRICTION:**

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes

Restricted to retail pharmacy only: No

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments: \_\_\_\_\_

**SDS Hazard Classification**

Organic  Corrosive

Inorganic  Oxidizer

Steroid/Androgen  Contact Hazard

Aerosol Class; Identify NFPA Storage Level: \_\_\_\_\_

Is the product a NIOSH hazardous drug? \_\_\_\_\_

If yes, indicate which: \_\_\_\_\_

**Hazardous Waste Identification**

EPA Hazardous Waste Code: NA

**REMS or REGISTRY RESTRICTIONS**

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry? \_\_\_\_\_

Website URL: \_\_\_\_\_

Comments / Details: (For example, iPledge program?)  
\_\_\_\_\_

**REMS:** \_\_\_\_\_

REMS Program Manager Name: \_\_\_\_\_ Phone: \_\_\_\_\_

Supplier Manages REMS registry exclusively: No

Wholesale distributor support: No

Provider Name: \_\_\_\_\_

Site Enrollment Number assigned by Supplier: \_\_\_\_\_

DEA #: No

PCPDP #: No

NPI #: No

Comments \_\_\_\_\_

**Registry:** No

Registry Program Contact Name: \_\_\_\_\_ Phone: \_\_\_\_\_

Comments \_\_\_\_\_

**RETURN INSTRUCTIONS**

Contact tel. # if product received damaged: 732-529-0430

Is product returnable for credit: Yes

URL/Link to returns policy: contact - customerservice@camberpharma.com

Special regulations or returns requirements for this product in certain states? No

If so, which states? Other requirements? Comments? \_\_\_\_\_

**MISCELLANEOUS NOTES and/or Image of Product Barcode:**

\_\_\_\_\_

**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																																		
<p>Purchase orders may be accepted by:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">a. EDI</td> <td style="width: 10%; text-align: center;"><input type="checkbox"/> Yes</td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> </tr> <tr> <td>b. Autofax</td> <td style="text-align: center;"><input type="checkbox"/> No</td> <td>Fax Number:</td> <td colspan="3" style="border: 1px solid black; height: 20px;"></td> </tr> <tr> <td>c. Fax</td> <td style="text-align: center;"><input type="checkbox"/> Yes</td> <td>Fax Number:</td> <td colspan="3" style="border: 1px solid black; height: 20px;"></td> </tr> <tr> <td>d. Phone only</td> <td style="text-align: center;"><input type="checkbox"/> No</td> <td>Phone No.:</td> <td colspan="3" style="border: 1px solid black; height: 20px;"></td> </tr> <tr> <td>e. Supplier Web Site only</td> <td style="text-align: center;"><input type="checkbox"/> No</td> <td>Site Address:</td> <td colspan="3" style="border: 1px solid black; height: 20px;"></td> </tr> </table> <p>Minimum Order Quantity: <input type="text" value="case pack"/></p> <p>Supplier's Customer Service Number: <input type="text" value="732-529-0430 x466 x465 x467 x470"/></p> <p>Contracted 3PL company / contact #:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Name:</td> <td style="border: 1px solid black; height: 20px;"></td> </tr> <tr> <td>Phone:</td> <td style="border: 1px solid black; height: 20px;"></td> </tr> </table>	a. EDI	<input type="checkbox"/> Yes					b. Autofax	<input type="checkbox"/> No	Fax Number:				c. Fax	<input type="checkbox"/> Yes	Fax Number:				d. Phone only	<input type="checkbox"/> No	Phone No.:				e. Supplier Web Site only	<input type="checkbox"/> No	Site Address:				Name:		Phone:		<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input type="text" value="2:30PM"/> Eastern</p> <hr/> <p>Shipping lead time of PO: <input type="text" value="24/48"/> Hours <input type="text" value=""/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/> No</p> <p>Ships for second day receipt: <input type="checkbox"/> No</p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/> Yes</p>
a. EDI	<input type="checkbox"/> Yes																																		
b. Autofax	<input type="checkbox"/> No	Fax Number:																																	
c. Fax	<input type="checkbox"/> Yes	Fax Number:																																	
d. Phone only	<input type="checkbox"/> No	Phone No.:																																	
e. Supplier Web Site only	<input type="checkbox"/> No	Site Address:																																	
Name:																																			
Phone:																																			
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing																																		
<p>Expedited freight fees billed with each order: <input type="checkbox"/> No</p> <p>Drop Ship service fee billed with each order: <input type="checkbox"/> No</p> <p>Drop Ship miscellaneous fees billed: <input type="checkbox"/> No</p> <p>Comments: <div style="border: 1px solid black; height: 80px; width: 100%;"></div></p>	<p><b>Overnight receipt available:</b> <input type="checkbox"/> Yes</p> <p>PO Receipt cut off time: <input type="text" value="2:30PM"/> Eastern</p> <p>Days of week overnight is available:</p> <table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 15px; text-align: center;"><input checked="" type="checkbox"/></td><td>Monday</td></tr> <tr><td style="text-align: center;"><input checked="" type="checkbox"/></td><td>Tuesday</td></tr> <tr><td style="text-align: center;"><input checked="" type="checkbox"/></td><td>Wednesday</td></tr> <tr><td style="text-align: center;"><input checked="" type="checkbox"/></td><td>Thursday</td></tr> <tr><td style="text-align: center;"><input checked="" type="checkbox"/></td><td>Friday</td></tr> </table> <p><b>Priority Overnight receipt available:</b> <input type="checkbox"/> Yes</p> <p>PO Receipt Cut off time: <input type="text" value="2:30PM EST"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/> No</p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;">Phone:</td> <td style="width: 10%; text-align: center;"><input type="checkbox"/> No</td> <td style="width: 10%;">Phone #:</td> <td style="width: 10%;"></td> </tr> <tr> <td>Fax:</td> <td style="text-align: center;"><input type="checkbox"/> Yes</td> <td>Fax #:</td> <td style="border: 1px solid black; text-align: center; width: 100px;">732-562-8788</td> </tr> <tr> <td>EDI:</td> <td style="text-align: center;"><input type="checkbox"/> Yes</td> <td></td> <td></td> </tr> </table> <p>Overnight Fees apply: <input type="checkbox"/> Yes</p> <p>Other fees apply: <input type="checkbox"/> No</p>	<input checked="" type="checkbox"/>	Monday	<input checked="" type="checkbox"/>	Tuesday	<input checked="" type="checkbox"/>	Wednesday	<input checked="" type="checkbox"/>	Thursday	<input checked="" type="checkbox"/>	Friday	Phone:	<input type="checkbox"/> No	Phone #:		Fax:	<input type="checkbox"/> Yes	Fax #:	732-562-8788	EDI:	<input type="checkbox"/> Yes														
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EDI:	<input type="checkbox"/> Yes																																		
Class of Trade Restriction:																																			
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> No</p> <p>Restricted to retail pharmacy only: <input type="checkbox"/> Yes</p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> No</p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/> No</p> <p>Comments: <div style="border: 1px solid black; height: 80px; width: 100%;"></div></p>																																			
Other Data Information Required to Process PO:	Return Instructions																																		
<p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p>Contact # if product is received damaged: <input type="text" value="732-529-0430"/></p> <p>Is product returnable for credit: <input type="checkbox"/> Yes</p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> Yes</p> <p>If so, which states? Other requirements? Comments?  <div style="border: 1px solid black; height: 40px; width: 100%;"></div> </p>																																		
Miscellaneous Notes:	ADDITIONAL INFORMATION																																		
<div style="border: 1px solid black; height: 80px; width: 100%;"></div>	<p>Is product order for scheduled patient procedure? <input type="checkbox"/> No</p> <p>Is product order for restocking purposes? <input type="checkbox"/> No</p>																																		