



Date: 9/1/2026

SPECIAL HANDLING AND STORAGE REQUIREMENTS*					
Company Name: Camber Pharmaceuticals, Inc.					
Application Number for NDA/ANDA/BLA; PMA/510(k): 203047		Application: ANDA			
Medical Device Class, if applicable:		NDA 505(b) Type: NOT APPLICABLE			
DUNS: 11-856-3719					
Proprietary Name (If Applicable) and Established Name: Valacyclovir Tablets, USP 1 gram					
Selling Unit NDC: 31722-705-90		Unit of Use NDC: 31722-705-90	UPC: 331722705905		
UDI		CVX Code:	MXV Code:		
Description: Valacyclovir Tablets, USP 1 gram					
Active Ingredient(s): Valacyclovir hydrochloride, USP					
URL for Additional Product Information: www.camberpharma.com					
Address: 800 Centennial Ave, Suite 1		Address 2:			
City: Piscataway		State: NJ Zip: 08854			
Key Contact: Customer Service		Email: customerservice@camberpharma.com			
Phone Number: 1-866-827-3647		Fax: 732-562-8788			
Product Therapeutic Classification: Deoxynucleoside analogue DNA polymerase inhibitor					
ADDITIONAL PRODUCT INFORMATION					
The product is? a legend device? No if yes, enter class # a product kit? No if yes, list NDCs of component parts reverse numbered? No co-licensed? No latex-free? Yes preservative-free? Yes correctional institution block? No opioid? No Cannabinoid? No		Is the Product... Direct-Ship Only Is the Product... Unit of Use Orphan Drug Status FDA Approval Status Allergens Present Country of Origin India Is this product covered under the Trade Agreements Act (TAA)? No			
PRODUCT DESCRIPTION INFORMATION					
Size: 90 ct					
Strength: 1 gram					
Dosage Form: Film coated tablet					
Product Shape: Capsule					
Product Color: White to off-white					
Product Imprint: Debossed with "Y" on one side and "B7" on other side with partial scorebar on both sides.					
FOR GENERIC DRUG PRODUCTS					
I. Orange Book Rating: AB		Authorized Generic *If Authorized Generic, other section fields are not applicable			
II. Generic Equivalent to What Brand?: Valtrex					
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION					
Does supplier meet DSCSA definition of manufacturer? Yes		GLN: 0331722498975			
Is product exempt from DSCSA? No		GCP:			
If yes, select exemption: Other exemption - Write in:					
Is product repackaged? No		If yes, was original product purchased direct from mfr?			
Is product sold by manufacturer's exclusive distributor? Yes		Provide source manufacturer for repackaged product			
Has FDA granted waiver/exception/exemption for product? No					
If yes, attach documentation from FDA.					
GTIN AND HIBCC PRODUCT INFORMATION					
Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
x Item/Each	N	1		00331722705905	00331722705905
x Box/Carton/Bundle/Inner Pack					
x Case	N	24		20331722705909	
x Pallet					
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) Notes 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? 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): 24 Months					
ORDER INFORMATION					
Unit of Sale		What is the NDC selling unit?			
x Bottle		1 Bottle of 90 Tablets			
Box/Carton		(Write-in, e.g. 1 Box of 10 Vials)			
Ampule					
Glass					
Tube					
Vial Liquid Sgl					
Vial Liquid Multi					
Vial Powder Sgl					
Vial Powder Multi					
Other: Write In					
Minimum order quantity?		Yes			
If Yes, how many of which package type?					
24 Each					
Inner/Carton/Pack					
Case					
PHARMACY ORDER / BILL UNIT					
Rec. sell unit to customer?		Rx billing unit to pharmacy:			
(Write-in, e.g. 1 Vial)		Each			
HCPCS J-Code:		Gram			
		Milliliter			
ITEM AND PACKING INFORMATION					
	Weight Lbs.	Dimensions (US msmts.)		Volume (Cube)	Saleable # Pieces
	Depth	Width	Height		
Item/Each:	0.38	2.25	2.25	5.5	27.84 1
Box/Carton/Bundle/ Inner Pack:					
Case:	9.65	14	9.5	6	798.00 24
Pallet:					
COST INFORMATION			WHOLESALER USE ONLY:		
Regular Cost		Vendor #:			
Invoice Cost (WAC) (\$)	\$55.00	Whsl. Code #:			
As of date:	9/1/2026	Fineline Code:			

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature:

Signature:



Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

- a. Cytotoxic?
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?
Is the product a CA Prop 65 carcinogen?
Is the product a CA Prop 65 reproductive toxicant?
Does the product label bear a CA Prop 65 warning?

- c. Contact Hazard?
- d. Does this product require special clean-up instructions?
(If yes, attach SDS with special instructions.)
- e. Does the product contain DEHP?

Is this product regulated for shipment by DOT?
(if yes, answer a-e below and provide SDS)

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?

Is this product regulated for shipment by IATA?
(if yes, answer a-e below and provide SDS)

- 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?

RQ Threshold:

Is this a marine pollutant?

Is this product shipped utilizing an authorized DOT exception or Special Permit?

- (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? Controlled Substance Code
- Controlled by State(s)? Listed Chemical (List I or II)
- ARCOS Reportable? If yes, indicate which:
- Schedule No. Is it a scheduled listed chemical product?:

CLASS OF TRADE RESTRICTION:

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

Restricted to retail pharmacy only:

Restricted to hospital, clinics, and physician offices only:

Restricted from US territories? (explain in comments)

Comments:

SDS Hazard Classification

- ☒ Organic Corrosive
☐ Inorganic Oxidizer
☐ Steroid/Androgen Contact Hazard

Does the product have an Aerosol class? If yes,
identify NFPA Storage Level:

NFPA Storage Level:

Is the product a NIOSH hazardous drug?
If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code:

Waste Characteristics

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

If Yes, is it managed with a pharmacy registry?

Website URL:

Med Guide Required

Limited Distribution Requirement

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

REMS:

REMS Program Manager Name:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:

Site Enrollment Number assigned
by Supplier:

Phone:

DEA #:

NCPDP#:

NPI #:

Comments

Registry:

Registry Program Contact Name:

Phone:

Comments

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit:

URL/Link to returns policy:

Special regulations or returns requirements for this
product in certain states?

If so, which states? Other requirements? Comments:

MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE



Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

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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 ☐ c. Fax ☐ d. Phone only ☐ e. Supplier Web Site only ☐ Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone: Fax Number: Fax Number: Phone No.: Site Address:	Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Days Ships same day for next day receipt: ☐ Ships for second day receipt: ☐ Ships regular ground for 3-10 days receipt: ☐
Expedited Freight Charges or Other Designated Drop Ship Fees: Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight and Priority Overnight PO Processing Overnight receipt available: ☐ PO Receipt cut off time: Days of week overnight is available: ☐ Monday ☐ Tuesday ☐ Wednesday ☐ Thursday ☐ Friday Priority Overnight receipt available: ☐ PO Receipt Cut off time: Saturday Overnight receipt available: ☐ PO Receipt Cut off time: Order receipt method: Phone: Phone #: Fax: Fax #: EDI: Overnight Fees apply: ☐ Other fees apply: ☐
Class of Trade Restriction: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices ☐ Restricted to retail pharmacy only: ☐ Restricted to hospital, clinics, and physician offices only: ☐ Restricted from US territories? (explain in comments) ☐ Comments:	
Other Data Information Required to Process PO: Patient Procedure Date: Physician Name: Physician/Clinic Phone #: Physician State License #: Physician/Clinic DEA #: Physician/Clinic Specialty:	Return Instructions Contact # if product is received damaged: Is product returnable for credit: ☐ URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? ☐ If so, which states? Other requirements? Comments?
Miscellaneous Notes:	ADDITIONAL INFORMATION Is product order for scheduled patient procedure? ☐ Is product order for restocking purposes? ☐