



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

Version 2024

Introduction Type: New Item

Final Version

Date: 1/9/2025

| PRODUCT INFORMATION | |
|--|--|
| Company Name: | Camber Pharmaceuticals, Inc. |
| Application Number for NDA/ANDA/BLA; PMA/510(k): | 203047 |
| Medical Device Class, if 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 |
| 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 |
| City: | Piscataway |
| Key Contact: | Customer Service |
| Phone Number: | 1-866-827-3647 |
| Product Therapeutic Classification: | Deoxynucleoside analogue DNA polymerase inhibitor |

| 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) | |
| Notes | |
| Is this product to be shipped to customers on ice? | <input type="checkbox"/> No |
| Is this product to be shipped to customers on dry ice? | <input type="checkbox"/> 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? | <input type="checkbox"/> No |
| d. Store product (unit of sale) upright? | |
| Protect product (unit of sale) from light? | <input type="checkbox"/> No |
| e. Shelf life: | <input type="checkbox"/> 24 Months |
| Initial shelf life at launch (if different): | <input type="checkbox"/> Months |

| ADDITIONAL PRODUCT INFORMATION | | PRODUCT DESCRIPTION INFORMATION | |
|---|------------------------------|---|--|
| The product is? | | Is the Product... Direct-Ship Only | |
| a legend device? | <input type="checkbox"/> No | Is the Product... Unit of Use | |
| if yes, enter class # | | Orphan Drug Status | |
| if yes, list NDCs of component parts | | FDA Approval Status | |
| reverse numbered? | <input type="checkbox"/> No | Allergens Present | |
| co-licensed? | <input type="checkbox"/> No | Country of Origin | India |
| latex-free? | <input type="checkbox"/> Yes | Is this product covered under the Trade Agreements Act (TAA)? | <input type="checkbox"/> No |
| preservative-free? | <input type="checkbox"/> Yes | | |
| correctional institution block? | <input type="checkbox"/> No | | |
| opioid? | <input type="checkbox"/> No | | |
| Cannabinoid? | <input type="checkbox"/> No | | |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? | <input type="checkbox"/> | | |
| If Unit Dose, indicate NDC here: | | | |
| | | Size: | 90 ct |
| | | Strength: | 1 gram |
| | | Dosage Form: | Film coated tablet |
| | | Product Shape: | Capsule |
| | | Product Color: | White to off-white |
| | | Product Imprint: | Debossed with '1' on one side and '87' on other side with partial scorebar on both sides |

| ORDER INFORMATION | |
|--|--|
| Unit of Sale | What is the NDC selling unit? |
| <input checked="" type="checkbox"/> Bottle | 1 Bottle of 90 Tablets |
| <input type="checkbox"/> Box/ Carton | (Write-in, e.g. 1 Box of 10 Vials) |
| <input type="checkbox"/> Ampule | |
| <input type="checkbox"/> Glass | Minimum order quantity? <input type="checkbox"/> Yes |
| <input type="checkbox"/> Tube | |
| <input type="checkbox"/> Vial Liquid Sgl | |
| <input type="checkbox"/> Vial Liquid Multi | If Yes, how many of which package type? |
| <input type="checkbox"/> Vial Powder Sgl | <input type="checkbox"/> 24 Each |
| <input type="checkbox"/> Vial Powder Multi | <input type="checkbox"/> Inner/ Carton/ Pack |
| <input type="checkbox"/> Other: Write In | <input type="checkbox"/> Case |

| FOR GENERIC DRUG PRODUCTS | |
|---|---|
| I. Orange Book Rating: | AB |
| II. Generic Equivalent to What Brand?: | Valtrex |
| <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="checkbox"/> | <input type="checkbox"/> Each |
| (Write-in, e.g. 1 Vial) | <input type="checkbox"/> Gram |
| HCPCS J-Code: | <input type="checkbox"/> Milliliter |

| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION | |
|--|------------------------------|
| Does supplier meet DSCSA definition of manufacturer? | <input type="checkbox"/> Yes |
| Is product exempt from DSCSA? | <input type="checkbox"/> No |
| If yes, select exemption: | |
| Other exemption - Write in: | |
| Is product repackaged? | <input type="checkbox"/> No |
| Is product sold by manufacturer's exclusive distributor? | <input type="checkbox"/> Yes |
| Has FDA granted waiver/exception/exemption for product? | <input type="checkbox"/> No |
| If yes, attach documentation from FDA. | |
| GLN: | 0331722498975 |
| GCP: | |
| If yes, was original product purchased direct from mfr? | <input type="checkbox"/> |
| Provide source manufacturer for repackaged product | |

| ITEM AND PACKING INFORMATION | | | | | | |
|----------------------------------|-------------|------------------------|-------|--------|---------------|-------------------|
| Item/Each: | Weight Lbs. | Dimensions (US msmts.) | | | Volume (Cube) | Saleable # Pieces |
| | | Depth | Width | Height | | |
| Box/ Carton/ Bundle/ Inner Pack: | 0.38 | 2.25 | 2.25 | 5.5 | 27.84 | 1 |
| Case: | 9.65 | 14 | 9.5 | 6 | 798.00 | 24 |
| Pallet: | | | | | | |

| GTIN AND HIBCC PRODUCT INFORMATION | | | | |
|---|---------------|-------------------|-------|----------------|
| Saleable Unit of Measure | RFID tag(Y/N) | Saleable Quantity | HIBCC | GTIN-14 |
| <input checked="" type="checkbox"/> Item/Each | N | 1 | | 00331722705905 |
| <input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack | N | 24 | | 20331722705909 |
| <input type="checkbox"/> Case | | | | |
| <input type="checkbox"/> Pallet | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

| COST INFORMATION | | WHOLESALE USE ONLY: | |
|-------------------------|----------|---------------------|--|
| Regular Cost | | Vendor #: | |
| Invoice Cost (WAC) (\$) | \$116.64 | Whsl. Code #: | |
| As of date: | 4/3/2017 | 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:



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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? 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? No
 - Does the product label bear a CA Prop 65 warning? No

- 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? (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? No

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? No

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

- Passenger No
- 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 Yes Controlled Substance Code
- Controlled by State(s)? No Yes Listed Chemical (List I or II) No Yes
- ARCOS Reportable? No Yes If yes, indicate which:
- Schedule No. 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 No
- Restricted to retail pharmacy only: No Yes
- Restricted to hospital, clinics, and physician offices only: No Yes
- Restricted from US territories? (explain in comments) No Yes

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: No
NFPA Storage Level:

Is the product a NIOSH hazardous drug? No
If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code: Waste Characteristics:

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No Yes
If Yes, is it managed with a pharmacy registry? No Yes
Website URL:

Med Guide Required No Yes
Limited Distribution Requirement No Yes
Comments / Details: (For example, iPledge program?)

REMS: No Yes
REMS Program Manager Name: Phone:
Supplier Manages REMS registry exclusively: No Yes
Wholesale distributor support: No Yes
Provider Name: DEA #:
Site Enrollment Number assigned by Supplier: NCPDP#:
NPI #:

Comments

Registry: No Yes
Registry Program Contact Name: Phone:
Comments

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 1-866-827-3647

Is product returnable for credit: No Yes

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

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

If so, which states? Other requirements? Comments?

MISCELLANEOUS NOTES and/or Image of Product Barcode:



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 |
|---|--|
| <p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="checkbox"/></p> <p>b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>c. Fax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/></p> <p>e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> | <p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p> |
| 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="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p> | <p>Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p>Priority Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: <input type="text"/></p> <p>Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p> |
| Class of Trade Restriction: | |
| <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input type="text"/></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"/></p> <p>Is product returnable for credit: <input type="checkbox"/></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"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p> |
| Miscellaneous Notes: | ADDITIONAL INFORMATION |
| <p><input type="text"/></p> | <p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p> |