



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

Version 2024 Introduction Type: New Item Final Version Date: 11/20/2024

PRODUCT INFORMATION

Company Name: Camber Pharmaceuticals, Inc. Application: ANDA
 Application Number for NDA/ANDA/BLA; PMA/510(k): 201107 NDA 505(b) Type: NOT APPLICABLE
 Medical Device Class, if applicable:
 DUNS: 11-856-3719
 Proprietary Name (If Applicable) and Established Name: Abacavir Oral Solution, USP 20 mg/mL
 Selling Unit NDC: 31722-562-24 Unit of Use NDC: 31722-562-24 UPC: 331722562249
 UDI
 Description: Abacavir Oral Solution, USP 20 mg/mL
 Active Ingredient(s): Abacavir sulfate, USP
 URL for Additional Product Information: www.camberpharma.com
 Address: 800 Centennial Ave, Suite 1 State: NJ Address 2:
 City: Piscataway Zip: 08854
 Key Contact: Customer Service Email: customerservice@camberpharma.com
 Phone Number: 1-866-827-3647 Fax: 732-562-8788
 Product Therapeutic Classification: Nucleoside analogue human immunodeficiency virus (HIV-1) reverse transcriptase 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: Do not freeze. May be refrigerated.
 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

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is? a legend device? if yes, enter class # a product kit? if yes, list NDCs of component parts reverse numbered? co-licensed? latex-free? preservative-free? correctional institution block? opioid? Cannabinoid?	<input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No	Is the Product... Is the Product... Orphan Drug Status FDA Approval Status Allergens Present Gluten, Corn, Alcohol, Wheat Country of Origin India Is this product covered under the Trade Agreements Act (TAA)? No	Direct-Ship Only Unit of Use Size: 240 mL Strength: 20 mg/mL Dosage Form: Clear oral solution Product Shape: N/A Product Color: Yellowish Product Imprint: N/A

ORDER INFORMATION

Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 Bottle of 240 mL Oral Solution
<input type="checkbox"/> Box/ Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	
<input type="checkbox"/> Vial Powder Sgl	
<input type="checkbox"/> Vial Powder Multi	
<input type="checkbox"/> Other: Write In	

Minimum order quantity? Yes

If Yes, how many of which package type?
 16 Each
 Inner/ Carton/ Pack
 Case

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: AA
 II. Generic Equivalent to What Brand?: Ziagen
 Authorized Generic *If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer? Each
 Gram
 Milliliter
 (Write-in, e.g. 1 Vial)
 HCPCS J-Code:

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? Yes
 Has FDA granted waiver/exception/exemption for product? No
 If yes, attach documentation from FDA.
 GLN: 0331722498975
 GCP:
 If yes, was original product purchased direct from mfr?
 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:	0.73	2.5	2.5	6	37.5	1
Case:	12.75	11	11	6.75	816.75	16
Pallet:						

GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	N	1		00331722562249	00331722562249
<input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack	N	16		30331722562240	
<input type="checkbox"/> Case					
<input type="checkbox"/> Pallet					

COST INFORMATION

Regular Cost
 Invoice Cost (WAC) (\$) \$125.48
 As of date: 9/15/2017

WHOLESALE USE ONLY:
 Vendor #:
 Whsl. Code #:
 Fineline Code:



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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 Yes

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 Yes
NFPA Storage Level:

Is the product a NIOSH hazardous drug? Yes No
If yes, indicate which: Group 2 items (non-antineoplastic that meets a hazard criterion)

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: Yes No

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:

