



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

Version 2021 Introduction Type: Final Version Date:

PRODUCT INFORMATION **SPECIAL HANDLING AND STORAGE REQUIREMENTS***

Company Name: Camber Pharmaceuticals, Inc. **Application:** ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 091677
Medical Device Class, if applicable:
DUNS: 11-856-3719
Proprietary Name (If Applicable) and Established Name: Lopinavir and Ritonavir Tablets, USP 200 mg/50 mg
Selling Unit NDC: 31722-556-12 **Unit of Use NDC:** 31722-556-12 **UPC:** 331722556125
UDI **CVX Code:** **MVX Code:**
Description: Lopinavir and Ritonavir Tablets, USP 200 mg/50 mg
Active Ingredient(s): Lopinavir, USP, Ritonavir, 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: HIV-1 protease inhibitor

a. Temperature – Indicate the USP temperature range for this product.
 Temperature Range:
 Other Temperature Range Requirement (write in):
 Notes:
 Is this product to be shipped to customers on ice?
 Is this product to be shipped to customers on dry ice?
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?
d. Store product (unit of sale) upright?
e. Shelf life:
 Protect product (unit of sale) from light?
 Initial shelf life at launch (if different):

| ADDITIONAL PRODUCT INFORMATION | | PRODUCT DESCRIPTION INFORMATION | |
|---|----------------------------------|---|---|
| The product is a legend device? if yes, enter class # | <input type="text" value="No"/> | Is the Product... Direct-Ship Only | <input type="text"/> |
| a product kit? if yes, list NDCs of component parts reverse numbered? | <input type="text" value="No"/> | Is the Product... Unit of Use | <input type="text"/> |
| co-licensed? | <input type="text"/> | Orphan Drug Status | <input type="text"/> |
| latex-free? | <input type="text" value="No"/> | FDA Approval Status | <input type="text"/> |
| preservative-free? | <input type="text" value="Yes"/> | Allergens Present | <input type="text" value="Alcohol"/> |
| correctional institution block? opioid? | <input type="text" value="No"/> | Country of Origin | <input type="text" value="India"/> |
| Cannabinoid? | <input type="text" value="No"/> | Is this product covered under the Trade Agreements Act (TAA)? | <input type="text" value="No"/> |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? | <input type="text"/> | Size: | <input type="text" value="120 ct"/> |
| If Unit Dose, indicate NDC here: | <input type="text"/> | Strength: | <input type="text" value="200 mg/50 mg"/> |
| | | Dosage Form: | <input type="text" value="Film coated tablet"/> |
| | | Product Shape: | <input type="text" value="Ovaloid"/> |
| | | Product Color: | <input type="text" value="Yellow"/> |
| | | Product Imprint: | <input type="text" value="Debossed with 'H' on one side and '70' on the other side"/> |

ORDER INFORMATION

| Unit of Sale | What is the NDC selling unit? |
|--|--|
| <input checked="" type="checkbox"/> Bottle | <input type="text" value="1 Bottle of 120 Tablets"/> (Write-in, e.g. 1 Box of 10 Vials) |
| <input type="checkbox"/> Box/Carton | |
| <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?
 If Yes, how many of which package type?
 Each
 Inner/ Carton/ Pack
 Case

FOR GENERIC DRUG PRODUCTS

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

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?
 (Write-in, e.g. 1 Vial)
 Rx billing unit to pharmacy:
 Each
 Gram
 Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?
 Is product exempt from DSCSA?
 If yes, select exemption:
 Other exemption - Write in:
 Is product repackaged?
 Is product sold by manufacturer's exclusive distributor?
 Has FDA granted waiver/exception/exemption for product?
 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: | 0.5 | 2.75 | 2.75 | 6 | 45.38 | 1 |
| Case: | 6.5 | 11.5 | 8.75 | 7 | 704.38 | 12 |
| Pallet: | | | | | | |

GTIN AND HIBCC PRODUCT INFORMATION

| Saleable Unit of Measure | Saleable Quantity | HIBCC | GTIN-14 | Unit of Use GTIN-14 |
|--|-------------------|-------|----------------|---------------------|
| <input checked="" type="checkbox"/> Item/Each | 1 | | 00331722556125 | 00331722556125 |
| <input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack | | | | |
| <input checked="" type="checkbox"/> Case | 12 | | 30331722556126 | |
| <input type="checkbox"/> Pallet | | | | |

COST INFORMATION **WHOLESALE USE ONLY:**

Regular Cost
 Invoice Cost (WAC) (\$)
 As of date:
Vendor #:
Whsl. Code #:
Fineline Code:



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

Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

| MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION | | | | | | | | | | | | | | | | | |
|--|---|---|------------------------------------|------------------------------------|-----------------------------------|---|---|--------------------------------|-----------------------------|-------------------|-----------------------------|-------------------------|----------------------|--------------|----------------------|---|-----------------------------|
| <p>Is this product (check all that apply):</p> <p>a. Cytotoxic? <input type="checkbox"/> No</p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? <input type="checkbox"/> No Is the product a CA Prop 65 reproductive toxicant? <input type="checkbox"/> No Does the product label bear a CA Prop 65 warning? <input type="checkbox"/> No</p> <p>c. Contact Hazard? <input type="checkbox"/> No</p> <p>d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) <input type="checkbox"/> No</p> <p>e. Does the product contain DEHP? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/></p> <p>Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/></p> <p>Is the product restricted for air shipment? If so, indicate restriction: <input type="checkbox"/> No</p> <p><input type="checkbox"/> Passenger <input type="checkbox"/> Cargo <input type="checkbox"/> Passenger & Cargo</p> <p>Is this a reportable quantity? <input type="checkbox"/> No RQ Threshold: <input type="text"/></p> <p>Is this a marine pollutant? <input type="checkbox"/> No</p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit? <input type="checkbox"/> No (if yes, identify method below)</p> <p><input type="checkbox"/> Limited Quantity <input type="checkbox"/> Consumer Commodity, ORM-D <input type="checkbox"/> Small Quantity (49 CFR 173.4) <input type="checkbox"/> Special Permit; DOT-SP <input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101); SP# <input type="text"/></p> | <div style="background-color: #002060; color: white; padding: 2px; text-align: center; font-weight: bold;">SDS Hazard Classification</div> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"><input checked="" type="checkbox"/> Organic</td> <td style="width: 50%; border: none;"><input type="checkbox"/> Corrosive</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Inorganic</td> <td style="border: none;"><input type="checkbox"/> Oxidizer</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Steroid/Androgen</td> <td style="border: none;"><input type="checkbox"/> Contact Hazard</td> </tr> </table> <p>Does the product have an Aerosol class? If yes, identify NFPA Storage Level: <input type="text"/> No</p> <p>NFPA Storage Level: <input type="text"/></p> <p>Is the product a NIOSH hazardous drug? <input type="checkbox"/> No If yes, indicate which: <input type="text"/></p> | <input checked="" type="checkbox"/> Organic | <input type="checkbox"/> Corrosive | <input type="checkbox"/> Inorganic | <input type="checkbox"/> Oxidizer | <input type="checkbox"/> Steroid/Androgen | <input type="checkbox"/> Contact Hazard | | | | | | | | | | |
| <input checked="" type="checkbox"/> Organic | <input type="checkbox"/> Corrosive | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Inorganic | <input type="checkbox"/> Oxidizer | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Steroid/Androgen | <input type="checkbox"/> Contact Hazard | | | | | | | | | | | | | | | | |
| Hazardous Waste Identification | | | | | | | | | | | | | | | | | |
| EPA Hazardous Waste Code: <input type="text"/> Waste Characteristics: <input type="text"/> | | | | | | | | | | | | | | | | | |
| REMS or REGISTRY RESTRICTIONS | | | | | | | | | | | | | | | | | |
| <p>Is there a REMS on this product? <input type="checkbox"/> No</p> <p>If Yes, is it managed with a pharmacy registry? Website URL: <input type="text"/></p> <p>Med Guide Required <input type="checkbox"/> No</p> <p>Limited Distribution Requirement <input type="checkbox"/></p> <p>Comments / Details: (For example, iPledge program?) <input type="text"/></p> <p>REMS: <input type="checkbox"/> No</p> <p>REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input type="checkbox"/></p> <p>Wholesale distributor support: <input type="checkbox"/></p> <p>Provider Name: <input type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input type="text"/></p> <p>Comments <input type="text"/></p> <p>Registry: <input type="checkbox"/> No</p> <p>Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/></p> <p>Comments <input type="text"/></p> | | | | | | | | | | | | | | | | | |
| RETURN INSTRUCTIONS | | | | | | | | | | | | | | | | | |
| <p>Contact tel. # if product received damaged: <input type="text"/> 1-866-827-3647</p> <p>Is product returnable for credit: <input type="checkbox"/> Yes</p> <p>URL/Link to returns policy: <input type="text"/> contact - customerservice@camberpharma.com</p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> No</p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p> | | | | | | | | | | | | | | | | | |
| ADD'L STORAGE INFORMATION | | | | | | | | | | | | | | | | | |
| <p>Is the Product...</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 30%;">Controlled Substance?</td> <td style="width: 10%;"><input type="checkbox"/> No</td> <td style="width: 30%;">Controlled Substance Code</td> <td style="width: 30%;"><input type="text"/></td> </tr> <tr> <td>Controlled by State(s)?</td> <td><input type="checkbox"/> No</td> <td>Listed Chemical (List I or II)</td> <td><input type="checkbox"/> No</td> </tr> <tr> <td>ARCOS Reportable?</td> <td><input type="checkbox"/> No</td> <td>If yes, indicate which:</td> <td><input type="text"/></td> </tr> <tr> <td>Schedule No.</td> <td><input type="text"/></td> <td>Is it a scheduled listed chemical product?:</td> <td><input type="checkbox"/> No</td> </tr> </table> | | Controlled Substance? | <input type="checkbox"/> No | Controlled Substance Code | <input type="text"/> | Controlled by State(s)? | <input type="checkbox"/> No | Listed Chemical (List I or II) | <input type="checkbox"/> No | ARCOS Reportable? | <input type="checkbox"/> No | If yes, indicate which: | <input type="text"/> | Schedule No. | <input type="text"/> | Is it a scheduled listed chemical product?: | <input type="checkbox"/> No |
| Controlled Substance? | <input type="checkbox"/> No | Controlled Substance Code | <input type="text"/> | | | | | | | | | | | | | | |
| Controlled by State(s)? | <input type="checkbox"/> No | Listed Chemical (List I or II) | <input type="checkbox"/> No | | | | | | | | | | | | | | |
| ARCOS Reportable? | <input type="checkbox"/> No | If yes, indicate which: | <input type="text"/> | | | | | | | | | | | | | | |
| Schedule No. | <input type="text"/> | Is it a scheduled listed chemical product?: | <input type="checkbox"/> No | | | | | | | | | | | | | | |
| CLASS OF TRADE RESTRICTION: | | | | | | | | | | | | | | | | | |
| <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Yes</p> <p>Restricted to retail pharmacy only: <input type="checkbox"/> No</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: <input type="text"/></p> | | | | | | | | | | | | | | | | | |
| MISCELLANEOUS NOTES and/or Image of Product Barcode: | | | | | | | | | | | | | | | | | |
| Release DATE | | | | | | | | | | | | | | | | | |



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

Version 2021

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