



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

Version 2021 Introduction Type: Final Version Date:

| PRODUCT INFORMATION | |
|---|--|
| Company Name: | Camber Pharmaceuticals, Inc. |
| Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): | 203835 |
| Medical Device Class, if applicable: | |
| DUNS: | 11-856-3719 |
| Proprietary Name (If Applicable) and Established Name: | Losartan Potassium Tablets, USP 25 mg |
| Selling Unit NDC: | 31722-700-10 |
| Unit of Use NDC: | |
| UPC: | 331722700108 |
| CVX Code: | |
| MXV Code: | |
| Description: | Losartan Potassium Tablets, USP 25 mg |
| Active Ingredient(s): | Losartan potassium, 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: | Angiotensin II receptor blocker (ARB) |

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

| 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" value="Neither"/> |
| a product kit? if yes, list NDCs of component parts reverse numbered? | <input type="text" value="No"/> | Is the Product... Orphan Drug Status | <input type="text" value="Neither"/> |
| co-licensed? | <input type="text" value="No"/> | FDA Approval Status | |
| latex-free? | <input type="text" value="No"/> | Allergens Present | <input type="text" value="Lactose"/> |
| preservative-free? | <input type="text" value="Yes"/> | Country of Origin | <input type="text" value="India"/> |
| correctional institution block? | <input type="text" value="No"/> | Is this product covered under the Trade Agreements Act (TAA)? | <input type="text" value="No"/> |
| opioid? | <input type="text" value="No"/> | Size: | <input type="text" value="1000 ct"/> |
| Cannabinoid? | <input type="text" value="No"/> | Strength: | <input type="text" value="25 mg"/> |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? | <input type="text" value="No"/> | Dosage Form: | <input type="text" value="Film coated tablet"/> |
| If Unit Dose, indicate NDC here: | | Product Shape: | <input type="text" value="Oval"/> |
| | | Product Color: | <input type="text" value="White to off-white"/> |
| | | Product Imprint: | <input type="text" value="Debossed with '1' on one side and '5' 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 1000 Tablets"/> |
| <input type="checkbox"/> Box/Carton | (Write-in, e.g. 1 Box of 10 Vials) |
| <input type="checkbox"/> Ampule | Minimum order quantity? <input type="text" value="Yes"/> |
| <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 | |
| | If Yes, how many of which package type? |
| | <input type="text" value="24"/> Each |
| | <input type="text" value="Inner/ Carton/ Pack"/> |
| | <input type="text" value="Case"/> |

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

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

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

| ITEM AND PACKING INFORMATION | | | | | | |
|----------------------------------|-------------|------------------------|-------|--------|---------------|-------------------|
| Item/Each: | Weight Lbs. | Dimensions (US msmts.) | | | Volume (Cube) | Saleable # Pieces |
| | | Depth | Width | Height | | |
| Item/Each: | 0.23 | 2.2 | 2.2 | 3.75 | 18.15 | 1 |
| Box/ Carton/ Bundle/ Inner Pack: | | | | | | |
| Case: | 6.4 | 13.5 | 9.5 | 5.25 | 673.31 | 24 |
| 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 | <input type="text" value="1"/> | | <input type="text" value="00331722700108"/> | |
| <input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack | | | | |
| <input checked="" type="checkbox"/> Case | <input type="text" value="24"/> | | <input type="text" value="20331722700102"/> | |
| <input type="checkbox"/> Pallet | | | | |

| COST INFORMATION | | WHOLESALE USE ONLY: | |
|-------------------------|---|---------------------|--|
| Regular Cost | | Vendor #: | |
| Invoice Cost (WAC) (\$) | <input type="text" value="\$140.45"/> | Whsl. Code #: | |
| As of date: | <input type="text" value="11/25/2015"/> | 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:

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"/> No</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"/> No</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? <input type="checkbox"/></p> <p>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"/> Fax Number: <input type="text"/> c. Fax <input type="checkbox"/> Fax Number: <input type="text"/> d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/> e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/> 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"/> | 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 Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/> |