

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

| Version 2021  |                                |                     |                               |   |   | Introduction Ty   | уре:              | New Item                              |                                      | x Final             | /ersion       |                    |               | Date:         | 6/23       | 3/2024     |
|---|--------------------------------|---------------------|-------------------------------|---|---|---|-------------------|---------------------------------------|--------------------------------------|---------------------|---------------|--------------------|---------------|---------------|------------|------------|
|   |                                |                     | PRODUCT INFORMA               | TION                                    |   |   |                   |                                       |                                      | SP                  | ECIAL HAN     | DLING AND STOR     | AGE REQUI     | REMENTS*      |            |            |
| Company Name: Camber Pharmaceuticals, Inc. Application: ANDA                                |                                |                     |                               |   | a. Temperature – Indicate the USP temperature range for this product. |   |                   |                                       |                                      |                     |               |                    |               |               |            |            |
| Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 213812                  |                                |                     |                               |   |   | Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F) |                   |                                       |                                      |                     |               |                    |               |               |            |            |
| Medical Device Class, if applicable:  |                                |                     |                               |   |   |   |                   |                                       |                                      |                     |               |                    |               |               |            |            |
| DUNS:   | 11-856-3719                    |                     |                               |   |   |   |                   |                                       |                                      | Other Tempera       | ure Range F   | equirement         |               |               |            |            |
| Proprietary Name (If Applicable) a  | and Established Na             | ame: Epler          | enone Tablets 50 mg           |   |   |   |                   |                                       |                                      | (write in)          |               |                    |               |               |            |            |
| Selling Unit NDC:   | 31722-050-90                   |                     | Unit of Use NDC               |   | 31722-050-90  |   | 331722            | 2050906                               |                                      | Notes               |               |                    |               |               |            |            |
| UDI   |                                |                     | CVX Code:                     |   |   | MVX Code:   |                   |                                       | Į.                                   |                     |               |                    |               |               |            |            |
| Description: Eplerenone Tablets 50 mg Is this product to be shipped to customers on ice? No |                                |                     |                               |   |   |   |                   | 1                                     |                                      |                     |               |                    |               |               |            |            |
| _   |                                |                     |                               |   |   |   |                   |                                       |                                      |                     |               | to customers on de |               |               | No         | 1          |
| Active Ingredient(s): Eplerenone  |                                |                     |                               |   |   |   |                   |                                       |                                      |                     |               |                    |               |               |            |            |
|   |                                |                     |                               |   |   | b. Contact fo   | or temperature ex | cursion que                           |                                      |                     |               |                    |               |               |            |            |
| URL for Additional Product Inforn   |                                | www.camberpharm     | a.com                         |   |   |   |                   |                                       |                                      | Name:               |               |                    | Soma Raju     |               |            |            |
| Address:  | 800 Centennial A<br>Piscataway | ve, Suite 1         |                               |   | State:  | Address 2:  | 7:                | 00054                                 |                                      | Number:             |               |                    | 732-529-042   |               |            |            |
| City:<br>Key Contact:   | Customer Service               | <u> </u>            |                               |   | Email:  | customerservice@  |                   | 08854                                 | Group E-mail: somaraju@heterousa.com |                     |               |                    |               |               |            |            |
| Phone Number:   | 1-866-827-3647                 | Fax: 732-562-8788   |                               |   | <u>s carribo</u>  | <u>Sipriamia.com</u>  | c Special re      | states?                               |                                      |                     | No            | 1                  |               |               |            |            |
| Product Therapeutic Classificatio   |                                | Selective aldostero | one receptor antagonist antih | vpertensive                             | -   |   |                   |                                       |                                      |                     |               |                    | No            | 1             |            |            |
| Trouble Thorapound Glacomound   | •••                            |                     |                               | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, |   |   |                   |                                       |                                      | Openial retaine     | roquiromoni   | o tor and product. |               |               |            | 1          |
|   | ADDITI                         | ONAL PRODUCT IN     | NFORMATION                    |   |   | PRODUCT D   | DESCRI            | IPTION INFORMATION                    | d. Store prod                        | duct (unit of sale) | upright?      |                    |               |               | No         | 1          |
| The product is?   |                                |                     | Is the Product                | Direct-Ship (                           | Only  |   |                   |                                       |                                      | Protect produc      |               | la) from light?    |               |               | No         | i          |
| a legend device?  |                                | No                  | Is the Product                | Unit of Use                             | Stilly  |   | 1                 | 90 ct                                 | e. Shelf life:                       | Frotect produc      | t (unit or sa | ie) iroin light?   |               |               | 24         | Months     |
| if yes, enter class #   |                                | 140                 | Orphan Drug Status            |   |   | Size:   |                   | 30 01                                 | c. onen me.                          | Initial shelf life  | at launch (i  | f different):      |               |               | 2-7        | Months     |
| a product kit?  |                                | No                  |                               |   |   |   |                   | 50 mg                                 |                                      |                     |               |                    |               |               |            |            |
| if yes, list NDCs of  |                                |                     | FDA Approval Status           |   |   | Strength:   |                   | -                                     |                                      |                     |               | ORDER INFORM       | IATION        |               |            |            |
| component parts   |                                |                     |                               |   |   | Dosage Form   | n.                | Film coated tablet                    |                                      |                     |               |                    |               |               |            |            |
| reverse numbered?   |                                | No                  |                               |   |   | 2 coage : ci.i.   | [                 |                                       |                                      | Unit of Sale        |               |                    | What is the   |               | unit?      |            |
| co-licensed?  |                                | No                  | Allergens Present             |   |   |   |                   |                                       |                                      | x Bottle            |               |                    | 1 Bottle of 9 |               |            |            |
| latex-free?   |                                | Yes                 | Dairy, Lac                    | tose, Casein                            |   | Product Shap  | pe:               | Round, biconvex                       |                                      | Box/C               |               |                    | (Write-in, e. | g. 1 Box of 1 | 0 Vials)   |            |
| preservative-free?<br>correctional institution block?                                       |                                | Yes                 |                               |   |   |   | -                 | Linktuallan                           |                                      | Ampu                |               |                    | Minimum       |               |            | Vee        |
| opioid?   |                                | No<br>No            |                               |   |   | Product Colo  | or:               | Light yellow                          |                                      | Tube                |               |                    | Minimum o     | der quantity  |            | Yes        |
| Cannabinoid?  |                                | No                  | Country of Origin             | India                                   |   |   | ŀ                 | Debossed with 'V' on one side         |                                      |                     | quid Sgl      |                    |               |               |            |            |
| If Unit Dose, is item bar coded to u  | unit dose for                  |                     | ,g                            |   |   | Product Impri   |                   | and '67' on the other side            |                                      |                     | quid Multi    |                    | If Yes, how   | many of whi   | ch package | type?      |
| hospital scanning?  |                                |                     | Is this product covered       | under the                               |   |   |                   |                                       |                                      |                     | owder Sgl     |                    |               | Each          |            | •          |
| If Unit Dose, indicate NDC here:  |                                |                     | Trade Agreements Act (        | TAA)?                                   | No  |   |                   |                                       |                                      | Vial P              | owder Multi   |                    |               | Inner/Cartor  | /Pack      |            |
|   |                                |                     |                               |   |   |   |                   |                                       |                                      | Other               | Write In      |                    |               | Case          |            |            |
|   |                                |                     | FOR GENERIC DRUG PF           | ODUCTS                                  |   |   |                   |                                       |                                      |                     |               |                    |               |               |            |            |
|   |                                |                     |                               |   |   | PHARMACY ORDER / BILL UNIT  |                   |                                       |                                      |                     |               |                    |               |               |            |            |
|   |                                |                     |                               |   | Aut   | horized Generic   |                   | horized Generic, other                |                                      |                     | PH            | ARMACY ORDER       | / BILL UNIT   |               |            |            |
| I. Orange Book Rating:  | AB                             |                     |                               |   |   |   | section           | n fields are not applicable           | Rec. sell uni                        | t to customer?      |               |                    | Rx billing u  |               | асу:       |            |
| II. Generic Equivalent to What Bra  | ınd?:                          | Inspra              |                               |   |   |   |                   |                                       |                                      |                     |               |                    |               | Each          |            |            |
| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION  |                                |                     |                               |   |   |   | (Write-in, e.g    | g. 1 Vial)                            |                                      |                     |               | Gram               |               |               |            |            |
|   |                                | DRUG SUPP           | LT CHAIN SECURITY ACT         | (DSCSA) INFO                            | RIMATION  |   |                   |                                       |                                      |                     |               |                    |               | Milliliter    |            |            |
| Does supplier meet DSCSA defini   | ition of manufactur            | rer?                | Yes                           |   | GLN:  | 0331722498975   |                   |                                       |                                      |                     | ITEN          | AND PACKING IN     | IFORMATIO     | N             |            |            |
| Is product exempt from DSCSA?   |                                |                     | No                            |   |   |   |                   |                                       |                                      |                     |               |                    |               |               |            |            |
| If ves. select exemption:   |                                |                     |                               |   | GCP:  |   |                   |                                       | 1                                    |                     |               | Dimensio           | ons (US msn   | nts.)         | Volume     | Saleable # |
| Other exemption - Write in:   |                                |                     |                               |   | GGF.  |   |                   |                                       | 1                                    | We                  | ight Lbs.     | Depth              | Width         | Height        | (Cube)     | Pieces     |
| Is product repackaged?  |                                |                     | No                            |   | If yes, was ori   | ginal product purc  | chased            |                                       | Item/Each:                           |                     | 0.00          |                    |               |               | I          |            |
| Is product sold by manufacturer's   | exclusive distribu             | itor?               | Yes                           |   | direct from mi  |   |                   |                                       |                                      |                     | 0.09          | 1.57               | 1.57          | 3.13          | 7.72       | 1          |
| Has FDA granted waiver/exceptio   |                                |                     | No                            |   | Provide source  | e manufacturer for  | r repacl          | kaged product                         | Box/Carton/                          | Bundle/             |               |                    |               |               |            |            |
| If yes, attach documentation from   | m FDA.                         |                     |                               |   |   |   |                   |                                       | Inner Pack:                          |                     |               |                    |               |               |            |            |
|   |                                |                     |                               |   |   |   |                   |                                       | Case:                                |                     | 2.5           | 10                 | 6.75          | 4.25          | 286.88     | 24         |
|   |                                | GT                  | IN AND HIBCC PRODUCT          | NFORMATION                              |   |   |                   |                                       |                                      |                     |               |                    |               |               |            |            |
| Saleable Unit of Measure  | _                              |                     |                               |   |   |   |                   |                                       | Pallet:                              |                     |               |                    |               |               |            |            |
| X Item/Each   | 8                              | Saleable Quantity   | HIBCC                         |   | GTIN  | N-14<br>N-1722050906  | 1                 | Unit of Use GTIN-14<br>00331722050906 |                                      |                     |               |                    |               |               |            |            |
| Box/Carton/Bundle/Inner Pack  |                                | -                   |                               |   | 0033  | 1122000900  | -                 | 0000172200000                         |                                      | COST INFO           | RMATION       |                    |               | WHOLESAL      | ER USE ONL | Y:         |
| X Case  |                                | 24                  |                               |   | 3033  | 1722050907  |                   |                                       |                                      |                     |               |                    |               |               | LA GOL ONE |            |
| Pallet  |                                |                     |                               |   |   |   |                   |                                       | Regular Cos                          | t                   |               |                    | Vendor #:     |               |            |            |
|   |                                |                     |                               |   |   |   |                   |                                       | Invoice Cost                         |                     |               | \$75.00            | Whsl. Code    | #:            |            |            |
|   |                                |                     |                               |   |   |   |                   |                                       |                                      |                     |               |                    | Fineline Co   |               |            |            |
|   |                                |                     |                               |   |   |   |                   |                                       | As of date:                          | 8/28/2              | 023           |                    | ļ             |               |            |            |
|   |                                |                     |                               |   |   |   |                   |                                       |                                      |                     |               |                    |               |               |            |            |
| ļl.   |                                |                     |                               |   |   |   |                   |                                       | 4                                    |                     |               |                    | <u> </u>      |               |            |            |
|   |                                | _                   | Attach copy of SAFETY D       | ATA SHEET (SI                           | OS) or non hazar  |   |                   | T, LABEL AND PHOTO OF P               | RODUCT PACK                          |                     | ODE.          |                    |               |               |            |            |
| *Please provide any additional inf  | formation on page              | 2.                  |                               |   |   | See new n 3 for l   | Design:           | ated 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   | SDS Hazard Classification   |  |  |  |  |  |  |
| 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?  No  Does the product label bear a CA Prop 65 warning?  No   | x     Organic     Corrosive       Inorganic     Oxidizer       Steroid/Androgen     Contact Hazard  |  |  |  |  |  |  |
| 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?   | Does the product have an Aerosol class? If yes, identify NFPA Storage Level:  NFPA Storage Level:   |  |  |  |  |  |  |
| 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  | Is the product a NIOSH hazardous drug?  If yes, indicate which:   |  |  |  |  |  |  |
| c. DOT Hazard Class d. Packing Group  | Hazardous Waste Identification  |  |  |  |  |  |  |
| e. Inhalation Hazard?  Is this product regulated for shipment by IATA?  No  | EPA Hazardous Waste Code: Waste Characteristics   |  |  |  |  |  |  |
| (if yes, answer a-e below and provide SDS) a. UN/Identification Number  | REMS or REGISTRY RESTRICTIONS   |  |  |  |  |  |  |
| b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?  | Is there a REMS on this product?  If Yes, is it managed with a pharmacy registry?  Website URL:   |  |  |  |  |  |  |
| Is the product restricted for air shipment? If so, indicate restriction:  Passenger Cargo Passenger & Cargo   | Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)   |  |  |  |  |  |  |
| 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) | REMS:  REMS Program Manager Name:  Supplier Manages REMS registry exclusively:  Wholesale distributor support:  Provider Name:  Site Enrollment Number assigned by Supplier:  No  Phone:  DEA #:  NCPDP#:  NPI #: |  |  |  |  |  |  |
| Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#  | Comments  |  |  |  |  |  |  |
| ADD'L STORAGE INFORMATION   | Registry:  Registry Program Contact Name:  Comments  No  Phone:   |  |  |  |  |  |  |
| Is the Product  |   |  |  |  |  |  |  |
| Controlled Substance Code Controlled by State(s)? ARCOS Reportable? Schedule No.  No Controlled Substance Code Listed Chemical (List I or II) No If yes, indicate which: Is it a scheduled listed chemical product?: No CLASS OF TRADE RESTRICTION:                           | RETURN INSTRUCTIONS  Contact tel. # if product received damaged:  I-866-827-3647  Is product returnable for credit:  Yes  |  |  |  |  |  |  |
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes  | URL/Link to returns policy:  contact - customerservice@camberpharma.com   |  |  |  |  |  |  |
| Restricted to retail pharmacy only:  Restricted to hospital, clinics, and physician offices only:  No   | Special regulations or returns requirements for this product in certain states?   |  |  |  |  |  |  |
| Restricted from US territories? (explain in comments)  No  Comments:  | If so, which states? Other requirements? Comments?  |  |  |  |  |  |  |
| MISCELLANE  | DUS NOTES and/or Image of Product Barcode:  |  |  |  |  |  |  |
|   |   |  |  |  |  |  |  |



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#### FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

| Order Method fo   | r Designated Drop Ship Product                   | Standard Order Receipt and Processing  |  |  |  |  |  |  |
|---|--|--|--|--|--|--|--|--|
| Purchase orders may be accepted by: a. EDI  |  | Purchase order daily receipt cut off time by supplier Cut off time:  |  |  |  |  |  |  |
| b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity:   | Fax Number: Fax Number: Phone No.: Site Address: | Shipping lead time of PO:  Hours  Days  Ships same day for next day receipt: Ships for second day receipt:   |  |  |  |  |  |  |
| F   | Name: Phone:                                     | Ships regular ground for 3-10 days receipt:  |  |  |  |  |  |  |
| Expedited Freight Charg   | ges or Other Designated Drop Ship Fees:          | Overnight and Priority Overnight PO Processing   |  |  |  |  |  |  |
| Expedited freight fees billed with each order:  |  | Overnight receipt available:   |  |  |  |  |  |  |
| Drop Ship service fee billed with each order:   |  | PO Receipt cut off time:   |  |  |  |  |  |  |
| Drop Ship miscellaneous fees billed: Comments:  |  | Days of week overnight is available:  Monday  Tuesday  Wednesday  Thursday  Friday   |  |  |  |  |  |  |
|   |  | Priority Overnight receipt available:  |  |  |  |  |  |  |
| Class   | of Trade Restriction:                            | PO Receipt Cut off time:   |  |  |  |  |  |  |
| No restriction: Select YES if sold to retail pharmacy only: Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician of Restricted from US territories? (explain in conficulty) Comments: | offices only:                                    | Saturday Overnight receipt available:  PO Receipt Cut off time: Phone: Fax: EDI:  Overnight Fees apply: Other fees apply:  |  |  |  |  |  |  |
| Other Data Infor  | rmation Required to Process PO:                  | Return Instructions  |  |  |  |  |  |  |
| Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:  |  | 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? |  |  |  |  |  |  |
| Mis   | scellaneous Notes:                               |  |  |  |  |  |  |  |
|   |  |  |  |  |  |  |  |  |
|   |  | ADDITIONAL INFORMATION   |  |  |  |  |  |  |
|   |  | Is product order for scheduled patient procedure? Is product order for restocking purposes?  |  |  |  |  |  |  |