

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

| Version 2021 | | | | | | Introduction Ty | pe: Post Launch Change | | x Final Version | | | Date: | 11/26 | 26/2024 |
|--|-----------------------------|---------------------|--|------------------------------|------------------|--|---|---|-------------------------------------|-----------------------|-----------------|-----------------------|----------------------|---------------------|
| | | | PRODUCT INFORMA | TION | | | | | SPECIAL HA | NDLING AND STO | RAGE REQUI | REMENTS* | | |
| Company Name: Camber Pharmaceuticals, Inc. Application: ANDA | | | | | | a. Temperat | a. Temperature – Indicate the USP temperature range for this product. | | | | | | | |
| Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 214467 | | | | | | Temperature Range Cold – between 2 and 8 C (36° – 46° F) | | | | | | | | |
| Medical Device Class, if applicable: | | | | | | | | | | | | | | |
| DUNS: | 11-856-3719 | | | | | | | | Other Temperature Range | Requirement | | | | om temperature (20° |
| Proprietary Name (If Applicable) a | and Established Na | me: Enala | april Maleate Oral Solution 1 r | ng/mL | | | | | (write in) | | heat. | | s. Protect from free | - |
| Selling Unit NDC: | 31722-020-15 | | Unit of Use NDC: | | 31722-020-15 | | 331722020152 | | Notes | | | | | storage shipping |
| UDI | | | CVX Code: | | | MVX Code: | | | | | methods (e.g. 0 | Cold Packs, Cold | Storage Trucks | .) |
| Description: | Enalapril Maleate | Oral Solution 1 mg/ | mL | | | | | | Is this product to be shippe | ed to customers on | ice? | | No* | 7 |
| | · · | | | | | | | | Is this product to be shippe | | | | No | 1 |
| Active Ingredient(s): Enalapril maleate, USP | | | | | | | | | | | | | | |
| | | | | | | | | b. Contact f | or temperature excursion quality | uestions: | | | | |
| URL for Additional Product Inform | | www.camberpharn | na.com | | | | | | Name: | | Soma Raju | | | |
| Address: | 800 Centennial Av | /e, Suite 1 | | | Ctata | Address 2: | 7 | | Number: Group E-mail: | | 732-529-04 | | | |
| City: | Piscataway Customer Service | | | | State: Email: | | Zip: 08854 camberpharma.com | _ | somaraju@heterousa.com | | | | | |
| Key Contact: Phone Number: | 1-866-827-3647 | | | | 732-562-8788 | <u>camberpriamia.com</u> | - Consider | c. Special regulations for product in any states? | | | | No | 7 | |
| Product Therapeutic Classification | | Angiotensin conve | erting enzyme (ACE) inhibitor | | l ax. | 732-302-0700 | | C. Special re | Special returns requirement | - | | | No | - |
| Product Therapeutic Classificatio | on: | Angioterisin conve | erting enzyme (ACE) minibitor | | | | | | Special returns requiremen | nts for this product? | | | INO | _ |
| | ADDITIO | ONAL PRODUCT II | NEORMATION | | | PRODUCT DE | ESCRIPTION INFORMATION | d Store pro | duct (unit of sale) upright? | | | | No | 7 |
| | ADDITI | ONALT NODOOT II | | Discoul Obis 0 | No. In . | TRODUCTO | ESSIM TISH IN SKIIIATISH | u. Store pro | | | | | | 4 |
| The product is? | | NI. | Is the Product | Direct-Ship C Unit of Use | only | | 450 | | Protect product (unit of s | sale) from light? | | | No | |
| a legend device? if yes, enter class # | | No | Is the Product Orphan Drug Status | Utilit of Use | | Size: | 150 mL | e. Shelf life: | Initial shelf life at launch | (if different). | | | 24 | Months Months |
| a product kit? | | No | Orphan Drug Status | | | | 1 mg/mL | - | initial shell life at launch | (ir different): | | | | Wonths |
| if yes, list NDCs of | | 140 | FDA Approval Status | | | Strength: | i iig/iiL | | | ORDER INFOR | MATION | | | |
| component parts | | | | | | | Clear, oral solution | | | | | | | |
| reverse numbered? | | No | | | | Dosage Form: | , , | | Unit of Sale | | What is the | NDC selling | unit? | |
| co-licensed? | | No | Allergens Present | | | | | _ | x Bottle | | 1 Bottle of 1 | 50 mL Oral S | Solution | |
| latex-free? | | Yes | | | | Product Shape | N/A | | Box/Carton | | (Write-in, e | .g. 1 Box of 1 | 0 Vials) | |
| preservative-free? | | No | | | | 1 Todact Gridge | | | Ampule | | | | | |
| correctional institution block? | | No | | | | Product Color | Colorless | | Glass | | Minimum o | rder quantity | y? | Yes |
| opioid? | | No | | | | | | | Tube | | | | | |
| Cannabinoid? | | No | Country of Origin | India | | Product Imprii | nt: N/A | | Vial Liquid Sgl | | | | | |
| If Unit Dose, is item bar coded to | unit dose for | | In this was done a service of a | and a settle a | | · · | | _ | Vial Liquid Multi | | | | ich package | type? |
| hospital scanning? | | | Is this product covered to Trade Agreements Act (| | No | | | | Vial Powder Sgl Vial Powder Mult | ut. | 12 | Each | -/Deal- | |
| If Unit Dose, indicate NDC here: | | | Trade Agreements Act (| IAA)! | INO | | | | Other: Write In | и | | Inner/Cartor Case | I/Pack | |
| | | | FOR GENERIC DRUG PR | ODUCTS | | | | | Other, Write III | | | Odsc | | |
| | | | TOR GENERIC DROGTR | 000013 | | | | | | | | | | |
| | | | | | Aut | horized Generic * | If Authorized Generic, other | | Р | HARMACY ORDER | R / BILL UNIT | | | |
| L Oranga Baak Batings | AB | | | _ | 7.00 | | section fields are not applicable | Pac sall un | it to customer? | | | | | , |
| I. Orange Book Rating: II. Generic Equivalent to What Bra | | Epaned | | | | | ••• | Nec. sen un | it to customer: | | KX billing u | init to pharm Each | acy: | |
| II. Generic Equivalent to What Bra | anur. | Lpaneu | | | | | | (Write-in, e. | 1 Vial) | | | Gram | | |
| | | DRUG SUPF | PLY CHAIN SECURITY ACT | (DSCSA) INFOR | RMATION | | | (************************************** | g v.c., | | | Milliliter | | |
| | | | | · / | | | | | | | | | | |
| Does supplier meet DSCSA defini | ition of manufactur | er? | Yes | | GLN: | 0860000397957 | | | ITE | M AND PACKING I | INFORMATIO | N | | |
| Is product exempt from DSCSA? | | | No | | | | | | | | | | | |
| If yes, select exemption: | | | | | GCP: | | | | | Dimens | sions (US msr | nts.) | Volume | Saleable # |
| Other exemption - Write in: | | | | | | | | | Weight Lbs. | Depth | Width | Height | (Cube) | Pieces |
| Is product repackaged? | | | No | | If yes, was ori | ginal product purch | ased | Item/Each: | 0.5 | 2.4 | 2.4 | 5.2 | 29.95 | 1 |
| Is product sold by manufacturer's | | | Yes | | direct from mf | | | | | 2.4 | 2.4 | 5.2 | 25.55 | ' |
| Has FDA granted waiver/exception | | oduct? | No | | Provide sourc | e manufacturer for | repackaged product | Box/Carton/ | Bundle/ | | | | | |
| If yes, attach documentation fro | m FDA. | | | | | | | Inner Pack: | | | | | | |
| | | 61 | TIN AND HIBCC PRODUCT I | NEORMATION | | | | Case: | 6.4 | 10.1 | 7.9 | 6.4 | 510.66 | 12 |
| | | G | TIN AND HIBCC PRODUCT I | NFORMATION | | | | Pallet: | | _ | - | | | - |
| Saleable Unit of Measure | 9 | aleable Quantity | HIBCC | | GTIN | L-1 <i>1</i> | Unit of Use GTIN-14 | railet. | | | | | | |
| X Item/Each | | 1 | TIIDCC | | | 31722020152 | 00331722020152 | | | | | | | |
| Box/Carton/Bundle/Inner Pack | | | | | 1 5000 | | | | COST INFORMATION | | | WHOLESAL | ER USE ONL | LY: |
| X Case | | 12 | | | 2033 | 1722020156 | | | | | | | | |
| Pallet | | | | | | | | Regular Cos | st . | | Vendor #: | | | |
| | | | | | | | | Invoice Cos | t (WAC) (\$) | \$489.74 | Whsl. Code | #: | | |
| | | | | | | | | - [1] | | | Fineline Co | de: | | |
| | | | | | | | | As of date: | 2/25/2022 | | | | | |
| | | | | | | | | - [] | | | | | | |
| <u> </u> | | | | | | | | | /.o.v.o | | | | | |
| 1 | | _ | Attach copy of SAFETY D | ATA SHEET (SE | or non hazar | | NSERT, LABEL AND PHOTO C | F PRODUCT PACE | | | | | | |
| *Please provide any additional inf | | | | | | See new n 3 for D | esignated 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? 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? No | 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 EPA Hazardous Waste Code: Waste Characteristics | | | | | | |
| e. Inhalation Hazard? Is this product regulated for shipment by IATA? No | EPA Hazardous waste Code: | | | | | | |
| (if yes, answer a-e below and provide SDS) | REMS or REGISTRY RESTRICTIONS | | | | | | |
| a. UN/Identification Number 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#: NCPDP#: NPI #: | | | | | | |
| Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP# | Comments Registry: No | | | | | | |
| or# | Registry: No Registry Program Contact Name: Phone: | | | | | | |
| ADD'L STORAGE INFORMATION | Comments | | | | | | |
| Is the Product Controlled Substance? 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 | Contact tel. # if product received damaged: Is product returnable for credit: RETURN INSTRUCTIONS 1-866-827-3647 Yes | | | | | | |
| CLASS OF TRADE RESTRICTION: | URL/Link to returns policy: | | | | | | |
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) No | contact - customerservice@camberpharma.com Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments? | | | | | | |
| Comments: | | | | | | | |
| | OUS NOTES and/or Image of Product Barcode: | | | | | | |
| Patients may store Enalapril Maleate Oral Solution at room temperature (20° to 25°C/ 68° to 77°F). If store | eu al room temperature, discard aπer ου days. | | | | | | |



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

| Order Method for Designated Drop S | nip 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: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone: | per: | Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt: |
| Expedited Freight Charges or Other Designa | ed Drop Ship Fees: | Overnight and Priority Overnight PO Processing |
| Expedited freight fees billed with each order: Drop Ship service fee billed with each order: | | Overnight receipt available: 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, hospitals, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments: | s and physician offices | Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply: |
| Other Data Information Required to F | rocess 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? |
| Miscellaneous Notes: | | |
| | | |
| | | ADDITIONAL INFORMATION |
| | | Is product order for scheduled patient procedure? Is product order for restocking purposes? |