

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

| Version 2021 | | | | | | Introduction Type: | Post Launch Change | | x Final Version | | | Date: | 11/20 | 0/2024 |
|--|-----------------------------|-------------------------|---------------------------------|----------------|------------------|---|--|-------------------|--------------------------------------|----------------------|---------------|----------------------|---------------|------------|
| | | | PRODUCT INFORMA | TION | | | | | SPECIAL HAN | IDLING AND STO | RAGE REQUI | REMENTS* | | |
| Company Name: Camber Pharmaceuticals, Inc. Application: ANDA | | | | | | a. Temperature – Indicate the USP temperature range for this product. | | | | | | | | |
| Application Number for NDA/AN | NDA/BLA (drug); PM | IA/510(k)(med devi | ce): | 212 | 2277 | | | | Temperature Range | Controlled Room | | and 25 C (68 | 3° – 77° F) | |
| Medical Device Class, if applica | | | | | | | | | · - | | | | | |
| DUNS: | 11-856-3719 | | | | | | | | Other Temperature Range | Requirement | | | | |
| Proprietary Name (If Applicable) | and Established Na | me: Venla | faxine Hydrochloride Extend | ed-Release Cap | sules, USP 75 | mg (base) | | | (write in) | | | | | |
| Selling Unit NDC: | 31722-003-30 | | Unit of Use NDC | | 31722-003-30 | | 22003308 | | Notes | | | | | |
| UDI | | | CVX Code: | | | MVX Code: | | | | | | | | |
| Description: | Venlafaxine Hydro | chloride Extended-F | Release Capsules, USP 75 r | ng (base) | | | | | Is this product to be shippe | d to customers on | ice? | | No | 1 |
| | | | | | | | | | Is this product to be shippe | | | | No | 1 |
| Active Ingredient(s): | | Venlafaxine hydrod | chloride, USP | | | | | | | | | | | |
| | | | | | | | | b. Contact for | r temperature excursion qu | estions: | | | | |
| URL for Additional Product Inform | | www.camberpharm | a.com | | | | | | Name: | | Soma Raju | | | |
| Address: | 800 Centennial Av | e, Suite 1 | | | State: | Address 2: NJ Zip: | 00054 | | Number: | | 732-529-04 | | | |
| City: | Piscataway Customer Service | | | | State: Email: | customerservice@camb | 08854 | | Group E-mail: | | somaraju@h | eterousa.com | | |
| Key Contact: Phone Number: | 1-866-827-3647 | | | | Fax: | 732-562-8788 | berphama.com | a Special rea | julations for product in any | ctotoc? | | | No | 1 |
| Product Therapeutic Classification | | Saratonin and naron | pinephrine reuptake inhibitor (| SNIDI\ | I ax. | 732-302-0700 | | c. Special reg | | | | | No | - |
| Product Therapeutic Classification | on: | Serotoriiri arid riorep | omeprime reuptake minibilor (| DINKI) | | | | | Special returns requirement | is for this product? | | | INO |] |
| | ADDITIO | ONAL PRODUCT IN | IEOPMATION | | | PPODUCT DESCR | RIPTION INFORMATION | d Store prod | uct (unit of sale) upright? | | | | No | 1 |
| | — ADDITIC | JAME I RODUCI IN | | Diseas Obj. | ml | - TRODUCT DESCR | MI HOW IN ONWATION | u. Store prod | | | | | | 1 |
| The product is? | | | Is the Product | Direct-Ship C | nly | | | | Protect product (unit of sa | ale) from light? | | | No | |
| a legend device? | | No | Is the Product | Unit of Use | | Size: | 30 ct | e. Shelf life: | halded about the at leasure to | | | | 24 | Months |
| if yes, enter class # a product kit? | | No | Orphan Drug Status | | | | 75 mg | | Initial shelf life at launch (| ir airrerent): | | | | Months |
| if yes, list NDCs of | | INO | FDA Approval Status | | | Strength: | 75 mg | | | ORDER INFOR | MATION | | | |
| component parts | | | 1 DA Approvai otatus | | | | Hard gelatin capsule | | | ONDER IIII ON | | | | |
| reverse numbered? | | No | | | | Dosage Form: | The general surprise | | Unit of Sale | | What is the | NDC selling | unit? | |
| co-licensed? | | No | Allergens Present | | | | | | x Bottle | | 1 Bottle of 3 | | | |
| latex-free? | | Yes | Cluton Duo | Alcohol, Sugar | | Product Shape: | Capsule | | Box/Carton | | (Write-in, e | .g. 1 Box of 1 | 0 Vials) | |
| preservative-free? | | Yes | Giuten, Dye, | Alconol, Sugar | | Froduct Snape. | | | Ampule | | | | | |
| correctional institution block? | • | No | | | | Product Color: | Peach opaque cap & | | Glass | | Minimum o | rder quantity | /? | Yes |
| opioid? | | No | | | | Troduct Golor. | white opaque body | | Tube | | | | | |
| Cannabinoid? | | No | Country of Origin | India | | Product Imprint: | Imprinted with 'V' on cap & '10' on body printed in black color | | Vial Liquid Sgl | | | | | |
| If Unit Dose, is item bar coded to | unit dose for | | | | | | on body printed in black color | | Vial Liquid Multi | | | | ich package t | type? |
| hospital scanning? | | | Is this product covered | | | | | | Vial Powder Sgl | | 24 | Each | | |
| If Unit Dose, indicate NDC here: | | | Trade Agreements Act | IAA)? | No | | | | Vial Powder Multi Other: Write In | | | Inner/Cartor Case | л/Раск | |
| | | | FOR GENERIC DRUG PF | ODUCTO | | | | | Other. Write in | | | Case | | |
| | | | FOR GENERIC DRUG PI | CODUCTS | | | | | | | | | | |
| | | | | | Διι | thorized Generic *If Au | uthorized Generic, other | | PI | ARMACY ORDER | R/BILL UNIT | | | |
| 1 | AB | | | _ | | | on fields are not applicable | Dan and white | to customer? | | | | | |
| I. Orange Book Rating: | | Effexor XR | | | | | | Rec. sell unit | to customer? | | Rx billing u | nit to pharm | acy: | |
| II. Generic Equivalent to What Bra | anu r: | Ellexul VK | | | | | | (Write-in, e.g. | 1 Vial) | | | Each Gram | | |
| | | DRUG SUPP | LY CHAIN SECURITY ACT | (DSCSA) INFOR | MATION | | | (vviite-iii, e.g. | . i viai) | | | Milliliter | | |
| | | | | (, | | | | | | | | | | |
| Does supplier meet DSCSA defin | nition of manufacture | er? | Yes | | GLN: | 0331722498975 | | | ITEN | AND PACKING | INFORMATIO | N | | |
| Is product exempt from DSCSA? | | | No | | | | | | | | | | | |
| If ves. select exemption: | | | | _ | GCP: | | | 1 | | 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 or | riginal product purchased | d | Item/Each: | 0.08 | 1 | | 3 | | |
| Is product sold by manufacturer's | s exclusive distribut | tor? | Yes | | direct from m | | | | 0.08 | 1.5 | 1.5 | 3 | 6.75 | 1 |
| Has FDA granted waiver/exception | | oduct? | No | | Provide sour | ce manufacturer for repa | ckaged product | Box/Carton/B | Sundle/ | | | | | |
| If yes, attach documentation fro | om FDA. | | | | | | | Inner Pack: | | | | | | |
| - | | | | | | | | Case: | 2.5 | 9.75 | 6.6 | 4.25 | 273.49 | 24 |
| | | GT | IN AND HIBCC PRODUCT | NFORMATION | | | | | | | - | | | |
| Saleable Unit of Measure | _ | | | | | | | Pallet: | | | | | | |
| | Sa | aleable Quantity | HIBCC | | | N-14 | Unit of Use GTIN-14 | | | | | | | |
| X Item/Each Box/Carton/Bundle/Inner Pack | | 1 | | | 003 | 31722003308 | 00331722003308 | | COST INFORMATION | | | WHO! ESAL | ER USE ONL | γ. |
| X Case | | 24 | | | 303 | 31722003309 | | | COST IN OKWATION | | | WIIOLLSAL | ER OSE ONE | |
| | | 2-7 | | | 303 | J., 2230000 | | Regular Cost | | | Vendor #: | | | |
| Pallet | | | | | | | | Invoice Cost | | \$8.40 | Whsl. Code | #- | | |
| Pallet | | | | | | | | | | | | | | |
| Pallet | | | | | | | | | | | Fineline Co | | | |
| Pallet | | | | | | | | As of date: | 12/1/2024 | | | | | |
| Paliet | | | | | | | | As of date: | 12/1/2024 | | | | | |
| Pallet | | | | | | | | As of date: | 12/1/2024 | | | | | |
| Pallet | | | Attach copy of SAFETY D | ATA SHEET (SD | S) or non haza | ard letter, PACKAGE INSE | RT, LABEL AND PHOTO OF F | | | | | | | |



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Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

| MATERIAL | HAZARD CLASSIFICATION and TRANSPORTATION | | | | | |
|--|--|--|--|--|--|--|
| Is this product (check all that apply): a. Cytotoxic? 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? | SDS Hazard Classification x Organic Corrosive 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? Is this product regulated for shipment by DOT? | identify NFPA Storage Level: NFPA Storage Level: Is the product a NIOSH hazardous drug? No | | | | | |
| (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class | If yes, indicate which: Hazardous Waste Identification | | | | | |
| d. Packing Group e. Inhalation Hazard? | EPA Hazardous Waste Code: Waste Characteristics | | | | | |
| 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? | REMS or REGISTRY RESTRICTIONS 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 | | | | | |
| | Registry Program Contact Name: Phone: | | | | | |
| ADD'L STORAGE INFORMATION | Comments | | | | | |
| Is the Product Controlled Substance? No Controlled Substance Code | RETURN INSTRUCTIONS | | | | | |
| Controlled by State(s)? ARCOS Reportable? Schedule No. No Listed Chemical (List I or II) If yes, indicate which: Is it a scheduled listed chemical product?: No CLASS OF TRADE RESTRICTION: | Contact tel. # if product received damaged: 1-866-827-3647 Yes | | | | | |
| | URL/Link to returns policy: | | | | | |
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Ye | contact - customerservice@camberpharma.com | | | | | |
| Restricted to retail pharmacy only: | Special regulations or returns requirements for this | | | | | |
| Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) No. | product in certain states? If so, which states? Other requirements? Comments? | | | | | |
| Comments: | | | | | | |
| MISCELL | NEOUS 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 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? |