

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

| | | | | | | Introduction Type: | New Item |] | x Final Version | | | Date: | 5/15 | /2025 |
|--|---|--|---|---------------|---|---|---|---|--|---|---|--|---------------------------------|---------------------------------|
| PRODUCT INFORMATION | | | | | | | SPECIAL HANDLING AND STORAGE REQUIREMENTS* | | | | | | | |
| Company Name: Camber Pharmaceuticals, Inc. ANDA | | | | | a. Temperature – Indicate the USP temperature range for this product. | | | | | | | | | |
| Application Number for NDA/ANI | DA/BLA; PMA/510(I | k): 079234 | | | | NDA 505(b) Type: | NOT APPLICABLE | - · | Temperature Range | Controlled Room | | and 25 C (68 | ° – 77° F) | |
| Medical Device Class, if applicab | | | | | | | | | | | | | | |
| DUNS: | 11-856-3719 | | | | | | | | Other Temperature Range F | Requirement | | | | |
| Proprietary Name (If Applicable) a | | ne: Torsemi | ide Tablets, USP 10 mg | | | | | | (write in) | | | | | |
| | 31722-530-01 | | Unit of Use NDC: | | | | 722530019 | | Notes | | | | | |
| UDI | | | CVX Code: | | | MVX Code: | | | | | | | | |
| Description: | Torsemide Tablets, | , USP 10 mg | | | | | | | Is this product to be shipped | | | | No | |
| | | | | | | | | - | Is this product to be shipped | to customers on o | dry ice? | | No | |
| Active Ingredient(s): | | Torsemide, USP | | | | | | | | | | | | |
| URL for Additional Product Inform | ation | www.camberpharma. | com | | | | | b. Contact for | temperature excursion que Name: | estions: | Soma Raju | | | |
| Address: | 800 Centennial Ave | | 0011 | | 1 | Address 2: | | + | Number: | | 732-529-042 | 3 | | |
| | Piscataway | -, | | | State: | | 08854 | - | Group E-mail: | | | neterousa.com | n | |
| Key Contact: | Customer Service | | | | | | | | | | | _ | | |
| Phone Number: | 1-866-827-3647 | | | | Fax: | 732-562-8788 | | c. Special reg | ulations for product in any | states? | | | No |] |
| Product Therapeutic Classification | n: | Loop diuretic | | | | | | _ | Special returns requirement | s for this product? | | | No | |
| | L | | | | 4 | | | _ | | | | | | - |
| | ADDITIO | ONAL PRODUCT INF | ORMATION | | | PRODUCT DESC | RIPTION INFORMATION | d. Store produ | uct (unit of sale) upright? | | | | No |] |
| The product is? | | | Is the Product | Direct-Ship C | nly | | | | Protect product (unit of sa | le) from light? | | | No | 1 |
| a legend device? | | No | Is the Product | Neither | | Size: | 100 ct | e. Shelf life: | | | | | 24 | Months |
| if yes, enter class # | | | Orphan Drug Status | | | 0120. | | | Initial shelf life at launch (| if different): | | | | Months |
| a product kit? | | No | | | | Strength: | 10 mg | | | ORDER INFORM | | | | |
| if yes, list NDCs of | | | FDA Approval Status | | | | Tablet | | | ORDER INFORM | MATION | | | |
| component parts reverse numbered? | | No | | | | Dosage Form: | Tablet | | Unit of Sale | | What is the | NDC selling | unit? | |
| co-licensed? | | No | Allergens Present | | | | | | x Bottle | | 1 Bottle of 1 | | | |
| latex-free? | | Yes | _ | | | | Oval | | Box/Carton | | | g. 1 Box of 1 | 0 Vials) | |
| preservative-free? | | Yes | Dairy, Lactose, | Alcohol, Renn | et | Product Shape: | | | Ampule | | | • | , | |
| correctional institution block? | | No | | | | Product Color: | White to off white | | Glass | | Minimum o | rder quantity | ? | Yes |
| opioid? | | No | | | | i iouuoi ooioii | | | Tube | | | | | |
| Cannabinoid? | | No | Country of Origin | India | | Product Imprint: | Debossed with '57' on scored side and 'H' on the opposite side | | Vial Liquid Sgl | | | | | |
| If Unit Dose, is item bar coded to u hospital scanning? | nit dose for | | la éhia unaduat anuanadu | n dan éh a | | | | | Vial Liquid Multi Vial Powder Sgl | | | many of whi Each | ch package | type? |
| If Unit Dose, indicate NDC here: | | | Is this product covered un Trade Agreements Act (T | | No | | | | Vial Powder Sgi Vial Powder Multi | | 24 | Lach Inner/Cartor | Pack | |
| il offit Dose, illucate NDC fiele. | | | | 70(): | NO | | | | Other: Write In | | | Case | /I dok | |
| | | | FOR GENERIC DRUG PRO | ODUCTS | | | | J | | | | | | |
| | | | I ON GENERIO BROOT R | 000010 | | | | | | | | | | |
| | | | | | | | | | | | | | | |
| I. Orange Book Rating: | | | | | Au | uthorized Generic *If A | uthorized Generic, other | | PH | ARMACY ORDER | / BILL UNIT | | | |
| | AB | | | | Au | | uthorized Generic, other tion fields are not applicable | Rec. sell unit | | ARMACY ORDER | | nit to pharm | acv: | |
| | AB nd?: | Demadex | | | A. | | | Rec. sell unit | | ARMACY ORDER | | nit to pharm | acy: | |
| II. Generic Equivalent to What Bran | | | | | · | | | Rec. sell unit | to customer? | ARMACY ORDER | | | acy: | |
| | | | Y CHAIN SECURITY ACT (I | DSCSA) INFOR | · | | | | to customer? 1 Vial) | ARMACY ORDER | | Each | acy: | |
| II. Generic Equivalent to What Bran | nd?: | DRUG SUPPLY | | DSCSA) INFOR | MATION | sec | | (Write-in, e.g. | to customer? 1 Vial) le: |] | Rx billing u | Each Gram Milliliter | acy: | |
| II. Generic Equivalent to What Bran Does supplier meet DSCSA definit | nd?: | DRUG SUPPLY | Yes | DSCSA) INFOR | · | | | (Write-in, e.g. | to customer? 1 Vial) le: | ARMACY ORDER | Rx billing u | Each Gram Milliliter | acy: | |
| II. Generic Equivalent to What Bran Does supplier meet DSCSA definit Is product exempt from DSCSA? | nd?: | DRUG SUPPLY | | DSCSA) INFOR | MATION GLN: | sec | | (Write-in, e.g. | to customer? 1 Vial) le: | AND PACKING I | Rx billing u | Each Gram Milliliter | | |
| II. Generic Equivalent to What Bran Does supplier meet DSCSA definit Is product exempt from DSCSA? If yes, select exemption: | nd?: | DRUG SUPPLY | Yes | DSCSA) INFOR | MATION | sec | | (Write-in, e.g. | to customer? 1 Vial) je: ITEN | AND PACKING I | Rx billing u | Each Gram Milliliter N | Volume | Saleable # |
| II. Generic Equivalent to What Bran Does supplier meet DSCSA definit Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: | nd?: | DRUG SUPPLY | Yes No | DSCSA) INFOR | GLN: GCP: | 0331722498975 | ion fields are not applicable | (Write-in, e.g. HCPCS J-Cod | to customer? 1 Vial) le: ITEN Weight Lbs. | AND PACKING I Dimensi Depth | Rx billing u | Each Gram Milliliter N nts.) Height | Volume (Cube) | Saleable # Pieces |
| II. Generic Equivalent to What Bran Does supplier meet DSCSA definit Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? | nd?: tion of manufacture | DRUG SUPPLY | Yes No No | | MATION GLN: GCP: If yes, was o | 0331722498975 | ion fields are not applicable | (Write-in, e.g. | to customer? 1 Vial) je: ITEN | AND PACKING I | Rx billing u | Each Gram Milliliter N | Volume | |
| II. Generic Equivalent to What Bran Does supplier meet DSCSA definit Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's | nd?: tion of manufacture exclusive distribut | DRUG SUPPLY | Yes No | | GLN: GCP: If yes, was o direct from n | sec 0331722498975 riginal product purchas | ed | (Write-in, e.g. HCPCS J-Cod | to customer? 1 Vial) te: ITEN Weight Lbs. 0.09 | AND PACKING I Dimensi Depth | Rx billing u | Each Gram Milliliter N nts.) Height | Volume (Cube) | Pieces |
| II. Generic Equivalent to What Bran Does supplier meet DSCSA definit Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? | nd?: tion of manufacture exclusive distribut n/exemption for pro | DRUG SUPPLY | Yes No No Yes | | GLN: GCP: If yes, was o direct from n | 0331722498975 | ed | (Write-in, e.g. HCPCS J-Cod | to customer? 1 Vial) te: ITEN Weight Lbs. 0.09 | AND PACKING I Dimensi Depth | Rx billing u | Each Gram Milliliter N nts.) Height | Volume (Cube) | Pieces |
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HDA Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

| Version 2024 For Designation | ated Drop Ship Only Products, Please Use Page 3 |
|---|--|
| MATERIAL HA | ZARD CLASSIFICATION and TRANSPORTATION |
| Is this product (check all that apply): a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No Is the product a CA Prop 65 reproductive toxicant? No Does the product label bear a CA Prop 65 warning? C. Contact Hazard? d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) | SDS Hazard Classification x Organic Inorganic Oxidizer Steroid/Androgen Contact Hazard Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No NFPA Storage Level: Image: Contact Hazard |
| e. Does the product contain DEHP? No Is this product regulated for shipment by DOT? No (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Decking Compa | Is the product a NIOSH hazardous drug? No 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 | 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? No 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 No Limited Distribution Requirement Image: 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) Special Permit; DOT-SP | REMS: No REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: Phone: Wholesale distributor support: Provider Name: Site Enrollment Number assigned Provider Name: by Supplier: Provider Name: Comments Provider Name: |
| Special Provision (listed in Column 7 of 49 CFR 172.101); | Registry: No Registry Program Contact Name: Phone: |
| ADD'L STORAGE INFORMATION | Comments |
| Is the Product Controlled Substance? Controlled Substance? No Listed Chemical (List I or II) ARCOS Reportable? 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: 1-866-827-3647 Is product returnable for credit: Yes URL/Link to returns policy: Yes |
| | |
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes Restricted to retail pharmacy only: No Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No Comments: | contact - customerservice@camberpharma.com Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments? |
| | |
| MISCELLANE | EOUS NOTES and/or Image of Product Barcode: |
| | |



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

| Version 2024 | FOR DESIGNATED DROP SHIP PRODUCT ONLY - | if not a designated drop ship, do not complete. |
|--|---|--|
| Order Method for | r Designated Drop Ship Product | Standard Order Receipt and Processing |
| . , | Fax Number: Fax Number: Phone No.: Site Address: | Purchase order daily receipt cut off time by supplier Cut off time: 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: |
| | hone: es or Other Designated Drop Ship Fees: | Overnight and Priority Overnight PO Processing |
| Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments: | | Overnight receipt available: |
| | | Priority Overnight receipt available: |
| No restriction: Select YES if sold to retail phan Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician o Restricted from US territories? (explain in con Comments: | ffices only: ments) | PO Receipt Cut off time: Image: Constraint of the constr |
| Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty: | mation Required to Process PO: | Return Instructions Return Instructions Contact # if product is received damaged: Is product returnable for credit: URL/Link to returns policy: URL/Link to returns policy: |
| Mis | scellaneous Notes: | |
| | | ADDITIONAL INFORMATION Is product order for scheduled patient procedure? Is product order for restocking purposes? |