



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

Version 2021 Introduction Type:   Final Version Date:

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*																																									
<b>Company Name:</b> <input type="text" value="Camber Pharmaceuticals, Inc."/> <b>Application:</b> <input type="text" value="ANDA"/> <b>Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):</b> <input type="text" value="079234"/> <b>Medical Device Class, if applicable:</b> <input type="text"/> <b>DUNS:</b> <input type="text" value="11-856-3719"/> <b>Proprietary Name (If Applicable) and Established Name:</b> <input type="text" value="Torsemide Tablets 5 mg"/> <b>Selling Unit NDC:</b> <input type="text" value="31722-529-01"/> <b>Unit of Use NDC:</b> <input type="text"/> <b>UPC:</b> <input type="text" value="331722529013"/> <b>UDI</b> <input type="text"/> <b>CVX Code:</b> <input type="text"/> <b>MVX Code:</b> <input type="text"/> <b>Description:</b> <input type="text" value="Torsemide Tablets 5 mg"/> <b>Active Ingredient(s):</b> <input type="text" value="Torsemide, USP"/> <b>URL for Additional Product Information:</b> <input type="text" value="www.camberpharma.com"/> <b>Address:</b> <input type="text" value="800 Centennial Ave, Suite 1"/> <b>Address 2:</b> <input type="text"/> <b>City:</b> <input type="text" value="Piscataway"/> <b>State:</b> <input type="text" value="NJ"/> <b>Zip:</b> <input type="text" value="08854"/> <b>Key Contact:</b> <input type="text" value="Customer Service"/> <b>Email:</b> <input type="text" value="customerservice@camberpharma.com"/> <b>Phone Number:</b> <input type="text" value="1-866-827-3647"/> <b>Fax:</b> <input type="text" value="732-562-8788"/> <b>Product Therapeutic Classification:</b> <input type="text" value="Loop diuretic"/>				<b>a. Temperature – Indicate the USP temperature range for this product.</b> Temperature Range <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/> Other Temperature Range Requirement (write in) <input type="text"/> Notes <input type="text"/> 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>b. Contact for temperature excursion questions:</b> <b>Name:</b> <input type="text" value="Soma Raju"/> <b>Number:</b> <input type="text" value="732-529-0423"/> <b>Group E-mail:</b> <input type="text" value="somaraju@heterousa.com"/> <b>c. Special regulations for product in any states?</b> <input type="text" value="No"/> Special returns requirements for this product? <input type="text" value="No"/> <b>d. Store product (unit of sale) upright?</b> <input type="text" value="No"/> <b>e. Shelf life:</b> <input type="text" value="No"/> Protect product (unit of sale) from light? <input type="text" value="No"/> Initial shelf life at launch (if different): <input type="text" value="24"/> Months <input type="text" value="24"/> Months																																									
ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION		ORDER INFORMATION		PHARMACY ORDER / BILL UNIT																																							
The product is a legend device? <input type="text" value="No"/> if yes, enter class # <input type="text"/> a product kit? <input type="text" value="No"/> if yes, list NDCs of component parts reverse numbered? <input type="text"/> co-licensed? <input type="text" value="No"/> latex-free? <input type="text" value="Yes"/> preservative-free? <input type="text" value="Yes"/> correctional institution block? <input type="text" value="No"/> opioid? <input type="text" value="No"/> Cannabinoid? <input type="text" value="No"/> If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="text"/> If Unit Dose, indicate NDC here: <input type="text"/>		<b>Is the Product... Direct-Ship Only</b> <input type="text"/> <b>Is the Product... Neither</b> <input type="text"/> <b>Orphan Drug Status</b> <input type="text"/> <b>FDA Approval Status</b> <input type="text"/> <b>Allergens Present</b> <input type="text" value="Dairy, Lactose, Alcohol, Rennet"/> <b>Country of Origin</b> <input type="text" value="India"/> Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="No"/>		<b>Size:</b> <input type="text" value="100 ct"/> <b>Strength:</b> <input type="text" value="5 mg"/> <b>Dosage Form:</b> <input type="text" value="Tablet"/> <b>Product Shape:</b> <input type="text" value="Oval"/> <b>Product Color:</b> <input type="text" value="White to off white"/> <b>Product Imprint:</b> <input type="text" value="Debossed with '56' on scored side and 'H' on the opposite side"/>		<b>Unit of Sale</b> <input checked="" type="checkbox"/> Bottle <input type="checkbox"/> Box/Carton <input type="checkbox"/> Ampule <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 <input type="text"/> <b>What is the NDC selling unit?</b> <input type="text" value="1 Bottle of 100 Tablets"/> (Write-in, e.g. 1 Box of 10 Vials) <b>Minimum order quantity?</b> <input type="text" value="Yes"/>		<b>If Yes, how many of which package type?</b> <input type="text" value="12"/> Each <input type="text"/> Inner/ Carton/Pack <input type="text"/> Case																																					
FOR GENERIC DRUG PRODUCTS																																													
<b>I. Orange Book Rating:</b> <input type="text" value="AB"/> <input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable <b>II. Generic Equivalent to What Brand?:</b> <input type="text" value="Demadex"/>																																													
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION																																													
<b>Does supplier meet DSCSA definition of manufacturer?</b> <input type="text" value="Yes"/> <b>Is product exempt from DSCSA?</b> <input type="text" value="No"/> <b>GLN:</b> <input type="text" value="0331722498975"/> <b>If yes, select exemption:</b> <input type="text"/> <b>Other exemption - Write in:</b> <input type="text"/> <b>GCP:</b> <input type="text"/> <b>Is product repackaged?</b> <input type="text" value="No"/> <b>Is product sold by manufacturer's exclusive distributor?</b> <input type="text" value="Yes"/> <b>Has FDA granted waiver/exception/exemption for product?</b> <input type="text" value="No"/> <b>If yes, attach documentation from FDA.</b> <input type="text"/> <b>If yes, was original product purchased direct from mfr?</b> <input type="text" value="No"/> <b>Provide source manufacturer for repackaged product</b> <input type="text"/>																																													
GTIN AND HIBCC PRODUCT INFORMATION																																													
<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>Saleable Unit of Measure</th> <th>Saleable Quantity</th> <th>HIBCC</th> <th>GTIN-14</th> <th>Unit of Use GTIN-14</th> </tr> </thead> <tbody> <tr> <td><input checked="" type="checkbox"/> Item/Each</td> <td><input type="text" value="1"/></td> <td><input type="text"/></td> <td><input type="text" value="00331722529013"/></td> <td><input type="text"/></td> </tr> <tr> <td><input checked="" type="checkbox"/> Box/Case/Bundle/Inner Pack</td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> </tr> <tr> <td><input checked="" type="checkbox"/> Case</td> <td><input type="text" value="12"/></td> <td><input type="text"/></td> <td><input type="text" value="10331722529010"/></td> <td><input type="text"/></td> </tr> <tr> <td><input type="checkbox"/> Pallet</td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> </tr> </tbody> </table>								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"/>	<input type="text" value="00331722529013"/>	<input type="text"/>	<input checked="" type="checkbox"/> Box/Case/Bundle/Inner Pack	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/> Case	<input type="text" value="12"/>	<input type="text"/>	<input type="text" value="10331722529010"/>	<input type="text"/>	<input type="checkbox"/> Pallet	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>													
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<b>Vendor #:</b> <input type="text"/> <b>Whsl. Code #:</b> <input type="text"/> <b>Fineline Code:</b> <input type="text"/>																																													

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:



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

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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
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?  No
  - 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?  No

- c. Contact Hazard?  No
- d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)  No
- e. Does the product contain DEHP?  No

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
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?  No

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?  No

Is the product restricted for air shipment? If so, indicate restriction:

- Passenger  No
- Cargo  No
- Passenger & Cargo  No

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
- Special Provision (listed in Column 7 of 49 CFR 172.101); SP#

### ADD'L STORAGE INFORMATION

Is the Product...

- Controlled Substance?  No  Yes  Controlled Substance Code
- Controlled by State(s)?  No  Yes  Listed Chemical (List I or II)  No  Yes
- ARCOS Reportable?  No  Yes  If yes, indicate which:
- Schedule No.  Is it a scheduled listed chemical product?:  No  Yes

### CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes  No
- Restricted to retail pharmacy only:  No  Yes
- Restricted to hospital, clinics, and physician offices only:  No  Yes
- Restricted from US territories? (explain in comments)  No  Yes

Comments:

### SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:  No   
NFPA Storage Level:

Is the product a NIOSH hazardous drug?  No   
If yes, indicate which:

### Hazardous Waste Identification

EPA Hazardous Waste Code:  Waste Characteristics

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?  No  Yes   
If Yes, is it managed with a pharmacy registry?  No  Yes   
Website URL:

Med Guide Required  No  Yes   
Limited Distribution Requirement  No  Yes   
Comments / Details: (For example, iPledge program?)

**REMS:**  No  Yes   
REMS Program Manager Name:  Phone:   
Supplier Manages REMS registry exclusively:  No  Yes   
Wholesale distributor support:  No  Yes   
Provider Name:   
Site Enrollment Number assigned by Supplier:

Comments

**Registry:**  No  Yes   
Registry Program Contact Name:  Phone:   
Comments

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:  1-866-827-3647

Is product returnable for credit:  Yes  No

URL/Link to returns policy:  contact - customerservice@camberpharma.com

Special regulations or returns requirements for this product in certain states?  No  Yes

If so, which states? Other requirements? Comments?

### MISCELLANEOUS 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 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"/>	<b>Purchase order daily receipt cut off time by supplier</b> 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"/>	<b>Overnight receipt available:</b> <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 <b>Priority Overnight receipt available:</b> <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> <b>Saturday Overnight receipt available:</b> <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
<input type="text"/>	Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>