



This product has two unique HDA forms.

One for a case of 12 bottles and one for a case of 24 bottles.

Both HDA sheets are shown below.

Please reference page 2 in this PDF for the 12 case pack, and page 5 for the 24 case pack.



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

Version 2021		Introduction Type: Post Launch Change		☒ Final Version		Date: 6/10/2024																																									
PRODUCT INFORMATION						SPECIAL HANDLING AND STORAGE REQUIREMENTS*																																									
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 079234 Medical Device Class, if applicable: DUNS: 11-856-3719 Proprietary Name (If Applicable) and Established Name: Torseme Tablets 20 mg Selling Unit NDC: 31722-531-01 Unit of Use NDC: UPC: 331722531016 UDI: CVX Code: MVX Code: Description: Torseme Tablets 20 mg Active Ingredient(s): Torseme, USP URL for Additional Product Information: www.camberpharma.com Address: 800 Centennial Ave, Suite 1 Address 2: City: Piscataway State: NJ Zip: 08854 Key Contact: Customer Service Email: customerservice@camberpharma.com Phone Number: 1-866-827-3647 Fax: 732-562-8788 Product Therapeutic Classification: Loop diuretic						a. Temperature – Indicate the USP temperature range for this product. Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F) Other Temperature Range Requirement (write in) Notes Is this product to be shipped to customers on ice? No Is this product to be shipped to customers on dry ice? No b. Contact for temperature excursion questions: Name: Soma Raju Number: 732-529-0423 Group E-mail: somaraju@heterousa.com c. Special regulations for product in any states? Special returns requirements for this product? No d. Store product (unit of sale) upright? No Protect product (unit of sale) from light? No e. Shelf life: 24 Months Initial shelf life at launch (if different): Months																																									
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION																																											
The product is? a legend device? No if yes, enter class # a product kit? No if yes, list NDCs of component parts reverse numbered? No co-licensed? No latex-free? Yes preservative-free? Yes correctional institution block? No opioid? No Cannabinoid? No If Unit Dose, is item bar coded to unit dose for hospital scanning? If Unit Dose, indicate NDC here: 				Is the Product... Direct-Ship Only Is the Product... Neither Orphan Drug Status FDA Approval Status Allergens Present Dairy, Lactose, Alcohol, Rennet Country of Origin India Is this product covered under the Trade Agreements Act (TAA)? No				Size: 100 ct Strength: 20 mg Dosage Form: Tablet Product Shape: Oval Product Color: White to off white Product Imprint: Debossed with '59' on scored side and 'H' on the opposite side																																							
FOR GENERIC DRUG PRODUCTS						ORDER INFORMATION																																									
I. Orange Book Rating: AB II. Generic Equivalent to What Brand?: Demadex						Unit of Sale <table border="1"><tr><td>☒</td><td>Bottle</td></tr><tr><td>☐</td><td>Box/ Carton</td></tr><tr><td>☐</td><td>Ampule</td></tr><tr><td>☐</td><td>Glass</td></tr><tr><td>☐</td><td>Tube</td></tr><tr><td>☐</td><td>Vial Liquid Sgl</td></tr><tr><td>☐</td><td>Vial Liquid Multi</td></tr><tr><td>☐</td><td>Vial Powder Sgl</td></tr><tr><td>☐</td><td>Vial Powder Multi</td></tr><tr><td>☐</td><td>Other: Write In</td></tr></table> What is the NDC selling unit? 1 Bottle of 100 Tablets (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity? Yes If Yes, how many of which package type? <table border="1"><tr><td>24</td><td>Each</td></tr><tr><td></td><td>Inner/ Carton/ Pack</td></tr><tr><td></td><td>Case</td></tr></table>		☒	Bottle	☐	Box/ Carton	☐	Ampule	☐	Glass	☐	Tube	☐	Vial Liquid Sgl	☐	Vial Liquid Multi	☐	Vial Powder Sgl	☐	Vial Powder Multi	☐	Other: Write In	24	Each		Inner/ Carton/ Pack		Case														
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☐	Other: Write In																																														
24	Each																																														
	Inner/ Carton/ Pack																																														
	Case																																														
PHARMACY ORDER / BILL UNIT						ITEM AND PACKING INFORMATION																																									
Rec. sell unit to customer? (Write-in, e.g. 1 Vial)						Rx billing unit to pharmacy: <table border="1"><tr><td>☐</td><td>Each</td></tr><tr><td>☐</td><td>Gram</td></tr><tr><td>☐</td><td>Milliliter</td></tr></table>		☐	Each	☐	Gram	☐	Milliliter																																		
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☐	Milliliter																																														
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION						COST INFORMATION																																									
Does supplier meet DSCSA definition of manufacturer? Yes Is product exempt from DSCSA? No If yes, select exemption: Other exemption - Write in: Is product repackaged? No Is product sold by manufacturer's exclusive distributor? Yes Has FDA granted waiver/exception/exemption for product? No If yes, attach documentation from FDA. 						Regular Cost Invoice Cost (WAC) (\$) \$21.38 As of date: 9/1/2009																																									
GTIN AND HIBCC PRODUCT INFORMATION						WHOLESALE USE ONLY:																																									
<table border="1"><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>☒ Item/Each</td><td>1</td><td></td><td>00331722531016</td><td></td></tr><tr><td>☐ Box/ Carton/ Bundle/ Inner Pack</td><td></td><td></td><td></td><td></td></tr><tr><td>☒ Case</td><td>24</td><td></td><td>20331722531010</td><td></td></tr><tr><td>☐ Pallet</td><td></td><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td><td></td></tr></tbody></table>						Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14	☒ Item/Each	1		00331722531016		☐ Box/ Carton/ Bundle/ Inner Pack					☒ Case	24		20331722531010		☐ Pallet																				Vendor #: Whsl. Code #: Fineline Code: 	
Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14																																											
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*Please provide any additional information on page 2. Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE. See new p. 3 for Designated Drop Ship Only. Signature: 																																															



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

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?	☐ 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?	☐ 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			
☐ Passenger & Cargo			
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	Controlled Substance Code	
Controlled by State(s)?	☐ No	Listed Chemical (List I or II)	☐ No
ARCOS Reportable?	☐ No	If yes, indicate which:	
Schedule No.		Is it a scheduled listed chemical product?:	☐ No
CLASS OF TRADE RESTRICTION:			
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:			
SDS Hazard Classification			
☒ Organic	☐ Corrosive		
☐ Inorganic	☐ Oxidizer		
☐ Steroid/Androgen	☐ 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	
If Yes, is it managed with a pharmacy registry?			
Website URL:			
Med Guide Required		☐ No	
Limited Distribution Requirement			
Comments / Details: (For example, iPledge program?)			
REMS:		☐ No	
REMS Program Manager Name:		Phone:	
Supplier Manages REMS registry exclusively:			
Wholesale distributor support:			
Provider Name:			
Site Enrollment Number assigned by Supplier:			
Comments:			
Registry:		☐ No	
Registry Program Contact Name:		Phone:	
Comments:			
RETURN INSTRUCTIONS			
Contact tel. # if product received damaged:		1-866-827-3647	
Is product returnable for credit:		☐ Yes	
URL/Link to returns policy:			
contact - customerservice@camberpharma.com			
Special regulations or returns requirements for this product in certain states?		☐ No	
If so, which states? Other requirements? Comments:			
MISCELLANEOUS NOTES and/or Image of Product Barcode:			

Release DATE



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

Version 2021

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 b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone: 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:
Expedited Freight Charges or Other Designated Drop Ship Fees: Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight and Priority Overnight PO Processing Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: ☐ Monday ☐ Tuesday ☐ Wednesday ☐ Thursday ☐ Friday Priority Overnight receipt available: PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Order receipt method: Phone: Phone #: Fax: Fax #: EDI: Overnight Fees apply: Other fees apply:
Class of Trade Restriction: 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) Comments:	
Other Data Information Required to Process PO: Patient Procedure Date: Physician Name: Physician/Clinic Phone #: Physician State License #: Physician/Clinic DEA #: Physician/Clinic Specialty:	Return Instructions 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?



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

Version 2024

Introduction Type: New Item

☒ Final Version

Date: 7/8/2026

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: Camber Pharmaceuticals, Inc.				Application: ANDA			
Application Number for NDA/ANDA/BLA; PMA/510(k): 079234				NDA 505(b) Type: NOT APPLICABLE			
Medical Device Class, if applicable:							
DUNS: 11-856-3719							
Proprietary Name (If Applicable) and Established Name: Torsemide Tablets, USP 20 mg							
Selling Unit NDC: 31722-531-01				Unit of Use NDC:			
UDI				UPC: 331722531016			
CVX Code:				MVX Code:			
Description: Torsemide Tablets, USP 20 mg							
Active Ingredient(s): Torsemide, USP							
URL for Additional Product Information: www.camberpharma.com							
Address: 800 Centennial Ave, Suite 1				Address 2:			
City: Piscataway				State: NJ Zip: 08854			
Key Contact: Customer Service				Email: customerservice@camberpharma.com			
Phone Number: 1-866-827-3647				Fax: 732-562-8788			
Product Therapeutic Classification: Loop diuretic							
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is?		Is the Product...		Size:		100 ct	
a legend device?		Is the Product...		Strength:		20 mg	
if yes, enter class #		Orphan Drug Status		Dosage Form:		Tablet	
a product kit?				Product Shape:		Oval	
if yes, list NDCs of component parts		FDA Approval Status		Product Color:		White to off white	
reverse numbered?				Product Imprint:		Debossed with '59' on scored side and '14' on the opposite side	
co-licensed?							
latex-free?		Allergens Present					
preservative-free?		Alcohol, Dairy, Lactose, Rennet					
correctional institution block?		Country of Origin		India			
opioid?							
Cannabinoid?							
If Unit Dose, is item bar coded to unit dose for hospital scanning?		Is this product covered under the Trade Agreements Act (TAA)?		No			
If Unit Dose, indicate NDC here:							
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating: AB				☐ Authorized Generic *If Authorized Generic, other section fields are not applicable			
II. Generic Equivalent to What Brand?: Demadox							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer?				GLN: 0331722498975			
Is product exempt from DSCSA?							
If yes, select exemption:				GCP:			
Other exemption - Write in:							
Is product repackaged?				If yes, was original product purchased direct from mfr?			
Is product sold by manufacturer's exclusive distributor?				Provide source manufacturer for repackaged product			
Has FDA granted waiver/exception/exemption for product?							
If yes, attach documentation from FDA.							
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure		RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14	
☒ Item/Each		N	1		00331722531016		
☒ Box/Carton/Bundle/Inner Pack		N	24		20331722531010		
☒ Case							
☒ Pallet							
ITEM AND PACKING INFORMATION							
	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces	
		Depth	Width	Height			
Item/Each:	0.18	1.5	1.5	4	9	1	
Box/Carton/Bundle/Inner Pack:							
Case:	4.8	9.5	6.5	5	308.75	24	
Pallet:							
COST INFORMATION				WHOLESALE USE ONLY:			
Regular Cost				Vendor #:			
Invoice Cost (WAC) (\$)				Whsl. Code #:			
				Fineline Code:			
As of date: 9/1/2009							

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)

Version 2024

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?

- 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?
(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?

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?

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

- ☐ Passenger
- ☐ Cargo
- ☐ Passenger & Cargo

Is this a reportable quantity?

RQ Threshold:

Is this a marine pollutant?

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

CLASS OF TRADE RESTRICTION:

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)

Comments:

SDS Hazard Classification

- ☒ Organic
- ☐ Inorganic
- ☐ Steroid/Androgen

Does the product have an Aerosol class? If yes,
identify NFPA Storage Level:

NFPA Storage Level:

Is the product a NIOSH hazardous drug?
If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code:

Waste Characteristics

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

If Yes, is it managed with a pharmacy registry?

Website URL:

Med Guide Required

Limited Distribution Requirement

Comments / Details: (For example, iPledge program?)

REMS:

REMS Program Manager Name:

Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:

Site Enrollment Number assigned
by Supplier:

Comments

Registry:

Registry Program Contact Name:

Phone:

Comments

RETURN INSTRUCTIONS

Contact tel. # if product 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 and/or Image of Product Barcode:

Release DATE



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 Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI ☐ b. Autofax ☐ c. Fax ☐ d. Phone only ☐ e. Supplier Web Site only ☐ Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone: 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: ☐
Expedited Freight Charges or Other Designated Drop Ship Fees: Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight and Priority Overnight PO Processing Overnight receipt available: ☐ PO Receipt cut off time: Days of week overnight is available: ☐ Monday ☐ Tuesday ☐ Wednesday ☐ Thursday ☐ Friday Priority Overnight receipt available: ☐ PO Receipt Cut off time: Saturday Overnight receipt available: ☐ PO Receipt Cut off time: Order receipt method: Phone: Phone #: Fax: Fax #: EDI: Overnight Fees apply: ☐ Other fees apply: ☐
Class of Trade Restriction: 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) ☐ Comments:	
Other Data Information Required to Process PO: Patient Procedure Date: Physician Name: Physician/Clinic Phone #: Physician State License #: Physician/Clinic DEA #: Physician/Clinic Specialty:	Return Instructions 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? ☐