

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:	
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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		
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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	
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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?