

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

Version 2024						Introduction Ty	pe: New Item		x Final Version			Date:	5/15/	/2025
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	RAGE REQUI	REMENTS*		
Company Name:	Camber Pharmac	euticals, Inc.				Application	on: ANDA	a. Temperature	a. Temperature – Indicate the USP temperature range for this product.					
Application Number for NDA/AN	IDA/BLA; PMA/510	(k): 0	79234			NDA 505(b) Type:	NOT APPLICABLE		remperature Range	Controlled Room		and 25 C (68	s° – 77° F)	
Medical Device Class, if applical	ble:													
DUNS:	11-856-3719								Other Temperature Range I	Requirement				
Proprietary Name (If Applicable) a		me: T	Forsemide Tablets, USP 20 mg						(write in)					
Selling Unit NDC:	31722-531-01		Unit of Use NDC:				331722531016	1	Notes					
UDI			CVX Code:			MVX Code:								
Description:	Torsemide Tablet	s, USP 20 mg							s this product to be shipped	d to customers on i	ce?		No	
								ļ. ļ	s this product to be shipped	d to customers on o	dry ice?		No	
Active Ingredient(s):		Torsemide, US	SP					h 0		41				
URL for Additional Product Inforn	nation:	www.camberp	harma com						emperature excursion qu Name:	estions:	Soma Raju			
Address:	800 Centennial A		Harma.com		1	Address 2:		<b>→</b> 1	lumber:		732-529-042	23		
City:	Piscataway	,			State:	NJ	Zip: 08854		Group E-mail:			neterousa.cor	n	
Key Contact:	Customer Service	•			Email:	customerservice@	camberpharma.com							
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special regulations for product in any states?						
Product Therapeutic Classificatio	n:	Loop diuretic						5	Special returns requirement	s for this product?			No	
					_			_						
	ADDITI	ONAL PRODUC	CT INFORMATION			PRODUCT D	ESCRIPTION INFORMATION	d. Store produc	t (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship C	nly				Protect product (unit of sa	ile) from light?			No	
a legend device?		No	Is the Product	Neither		Size:	100 ct	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status					1	nitial shelf life at launch (	if different):				Months
a product kit?		No	FD 4 4			Strength:	20 mg			ORDER INFORM	AATION			
if yes, list NDCs of component parts			FDA Approval Status				Tablet			ORDER INFORM	MATION			
reverse numbered?		No				Dosage Form:	Tablet	Ш ,	Jnit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present					'II r	x Bottle		1 Bottle of 1			
latex-free?		Yes		Alashal Dann	-4	Dundunt Chan	Oval		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes	Dairy, Lactose,	Alconol, Renn	et	Product Shap	е:		Ampule					
correctional institution block?		No				Product Color	White to off white		Glass		Minimum o	rder quantity	?	Yes
opioid?		No				1 100000 00.00			Tube					
Cannabinoid?		No	Country of Origin	India		Product Impri	nt: Debossed with '59' on scored side and 'H' on the opposite side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to unhospital scanning?	unit dose for		In this product covered u	ndor the					Vial Liquid Multi Vial Powder Sql			many of whi	ch package t	type?
If Unit Dose, indicate NDC here:			Is this product covered u Trade Agreements Act (1		No				Vial Powder Sgi Vial Powder Multi		24	Inner/Carton	/Pack	
III CHIL BOOG, III GIGAGO 115 C 116 C.				,.					Other: Write In			Case	ar don	
			FOR GENERIC DRUG PR	ODUCTS										
					Au		If Authorized Generic, other		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB						section fields are not applicable	Rec. sell unit to	customer?		Rx billing u	nit to pharm	асу:	
II. Generic Equivalent to What Bra	ınd?:	Demadex							Each					
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION					(Write-in, e.g. 1 Vial)				Gram					
		DRUG S	UPPLY CHAIN SECURITY ACT (	DSCSA) INFOR	RMATION			HCPCS J-Code	:	1		Milliliter		
Does supplier meet DSCSA defini	ition of manufactur	rer?	Yes	_	GLN:	0331722498975			ITEN	AND PACKING I	NEORMATIO	N		
Is product exempt from DSCSA?			No	-	02.11	0001122100010								
If yes, select exemption:					GCP:					Dimensi	ions (US msr	nts.)	Volume	Saleable #
Other exemption - Write in:					301 .			_	Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was o	riginal product purch	nased	Item/Each:	0.18	1.5	1.5	4	9	1
Is product sold by manufacturer's	exclusive distribu	itor?	Yes		direct from n				0.18	1.5	1.5	4	9	1
Has FDA granted waiver/exceptio		oduct?	No		Provide sour	rce manufacturer for	repackaged product	Box/Carton/Bur	ndle/					
If yes, attach documentation from	m FDA.							Inner Pack:						
			GTIN AND HIBCC PRODUCT IN	IEORMATION				Case:	4.8	9.5	6.5	5	308.75	24
			GTIN AND HIBCC PRODUCT II	NFORMATION				Pallet:						
Saleable Unit of Measure	RFID tag(Y/N)	Saleable	HIBCC		GTI	IN-14	Unit of Use GTIN-14	r allet.						
	3()	Quantity												
x Item/Each	N	1			003	331722531016								
Box/Carton/Bundle/Inner Pack									COST INFORMATION			WHOLESAL	ER USE ONL	.Y:
X Case	N	24			203	331722531010								
Pallet								Regular Cost	(AC) (\$)	004.00	Vendor #: Whsl. Code	#.		
								Invoice Cost (W	IAC) (φ)	\$∠1.38	Fineline Co			
								As of date:	9/1/2009		c.ine co	<b></b>		
											1			
					_			11			1			
			Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza	ard letter, PACKAGE I	NSERT, LABEL AND PHOTO OF	PRODUCT PACKAG	ING and BARCODE.					



### **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?	SDS Hazard Classification						
Is the product a CA Prop 65 carcinogen?  Is the product a CA Prop 65 reproductive toxicant?  No Does the product label bear a CA Prop 65 warning?  No	x Organic Corrosive Inorganic 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?  No	Does the product have an Aerosol class? If yes, identify NFPA Storage Level:  NFPA Storage Level:						
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	Is the product a NIOSH hazardous drug?  If yes, indicate which:						
c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Hazardous Waste Identification  EPA Hazardous Waste Code:  Waste Characteristics						
Is this product regulated for shipment by IATA?	LI A Hazardous Waste Code.						
(if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS						
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	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:						
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments  Registry:  No						
SF#	Registry:  Registry Program Contact Name:  No  Phone:						
ADD'L STORAGE INFORMATION	Comments						
Is the Product  Controlled Substance?  No Controlled Substance Code  Controlled by State(s)?  No Listed Chemical (List I or II)  No	RETURN INSTRUCTIONS						
ARCOS Reportable?  Schedule No.  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  Is product returnable for credit:  Yes						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes	URL/Link to returns policy:  contact - customerservice@camberpharma.com						
Restricted to retail pharmacy only:  No	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:							
MISCELLANI	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.

Purchase order ally receipt cut off time by supplier  a. EDI b. Autofax C. Fax Fax Number: C. Fax d. Phone only Phone only Supplier Veb Sile only Supplier Veb S	Order Method	for Designated Drop Ship Product	Standard Order Receipt and Processing
b. Autofax c. Fax d. Phone only e. Supplier Web Site only e. Supplier Web Site only supplier Subserver Service Number: Contracted 3PL company / contact #: Name: Phone Phone Phone Phone Phone Site Address Ships aame day for next day receipt: Ships regular ground for 3-10 days receipt: S	Purchase orders may be accepted by:		Purchase order daily receipt cut off time by supplier
d. Phone only e. Supplier Web Site only Site Address: Supplier Soustomer Service Number: Contracted 3PL company / contact # Name: Phone No.  Expedited freight Charges or Other Designated Drop Ship Fees:  Expedited freight fees billed with each order: Drop Ship service fee billed: Drop Ship service fee billed with each order: Drop Ship service fee billed: Drop Ship service fee billed with each order: Drop Ship service fee billed with each order: Drop Ship service fee billed: Drop Ship service fee billed with each order: Drop Ship service fee bil	a. EDI		Cut off time:
d. Phone only e. Suppler Web Site only Site Address:  Ships same day for next day receipt: Ships for second day receipt wallabe: Drownight for ships for ceipt: Ships for second day receipt wallabe: Drownight for ceipt valiable: Dry Receipt differs Dry Receipt day receipt wallabe: Dry Receip			
e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL. company / contact #: Name: Phone:  Expedited Freight Carlanges or Other Designated Drop Ship Fees:  Expedited Freight Carlanges or Other Designated Drop Ship Fees:  Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Drop Ship miscellaneous fees bi			Shipping lead time of PO: Hours Days
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