

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	IDLING AND STOR	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Applica					Application	on: ANDA	a. Temperatur	a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/AN	IDA/BLA; PMA/510(k): 0792	34			NDA 505(b) Type:	NOT APPLICABLE		Temperature Range	Controlled Room		and 25 C (68	3° – 77° F)	
Medical Device Class, if applical	ble:													
DUNS:	11-856-3719								Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a		me: Torse	emide Tablets, USP 100 mg						(write in)					
Selling Unit NDC:	31722-532-01		Unit of Use NDC:				331722532013		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Torsemide Tablets	s, USP 100 mg							Is this product to be shipped				No	
Active Ingredient(s):		Torsemide, USP							Is this product to be shipped	d to customers on	dry ice?		No	
Active ingredient(s):		Torsemide, USP						b. Contact for	temperature excursion qu	estions:				
URL for Additional Product Inforn	nation:	www.camberpharr	ma.com						Name:		Soma Raju			
Address:	800 Centennial Av	e, Suite 1				Address 2:			Number:		732-529-042	23		
City:	Piscataway				State:	NJ	Zip : 08854		Group E-mail:		somaraju@l	neterousa.com	<u>n</u>	
Key Contact:	Customer Service				Email:		camberpharma.com							1
Phone Number:	1-866-827-3647				Fax:	732-562-8788			ulations for product in any				No	
Product Therapeutic Classificatio	on:	Loop diuretic							Special returns requirement	ts for this product?			No	
	ADDITIO	ONAL PRODUCT I	NEOPMATION			PPODUCT D	ESCRIPTION INFORMATION	d Store produ	not (unit of cale) upright?				No	1
The area decades	ADDITIO	MAL PRODUCT I		Diseast Obj.	Nels .	PRODUCT DI	LOOKII HON INFORMATION	u. Store produ	ict (unit of sale) upright?]
The product is?			Is the Product	Direct-Ship C	nly		100 ct		Protect product (unit of sa	ale) from light?			No	
a legend device? if yes, enter class #		No	Is the Product Orphan Drug Status	Neither		Size:	100 ct	e. Shelf life:	Initial shelf life at launch (if different):			24	Months Months
a product kit?		No	Orphan Drug Status				100 mg	-	illitial Silell lile at laulich (ii dillerent).				WOILLIS
if yes, list NDCs of		110	FDA Approval Status			Strength:	g			ORDER INFOR	MATION			
component parts						Dosage Form:	Tablet							
reverse numbered?		No				Dosage Form.			Unit of Sale			NDC selling	unit?	
co-licensed?		No	Allergens Present					-	x Bottle		1 Bottle of 1			
latex-free?		Yes	Dairy, Lactose,	Alcohol, Renn	et	Product Shap	e: Oval		Box/Carton		(Write-in, e	g. 1 Box of 1	0 Vials)	
preservative-free? correctional institution block?		Yes	-			-	White to off white	-	Ampule Glass		Minimum	rder quantity		Yes
opioid?		No No				Product Color	. White to on white		Tube		Wilnimum o	ruer quantity	11	res
Cannabinoid?		No	Country of Origin	India			Debossed with '60' on scored side	-	Vial Liquid Sql					
If Unit Dose, is item bar coded to u	unit dose for		,g			Product Impri	nt: and 'H' on the opposite side		Vial Liquid Multi		If Yes, how	many of whi	ich package t	type?
hospital scanning?			Is this product covered u	nder the				-	Vial Powder Sgl			Each		***
If Unit Dose, indicate NDC here:			Trade Agreements Act (1		No				Vial Powder Multi			Inner/Cartor	n/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
					Aı	uthorized Generic	*If Authorized Generic, other		PH	HARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB						section fields are not applicable	Rec. sell unit t				nit to pharm	acv.	
II. Generic Equivalent to What Bra		Demadex						Tee. sen unit	o customer i		IXX billing u	Each	acy.	
II. Conone Equivalent to What Brance 1.				(Write-in, e.g. 1 Vial)			Gram							
		DRUG SUPF	PLY CHAIN SECURITY ACT (DSCSA) INFOR	RMATION			HCPCS J-Cod		_		Milliliter		
				_										
Does supplier meet DSCSA defini	ition of manufacture	er?	Yes No	_	GLN:	0331722498975			IIEN	AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			INU											
If yes, select exemption:					GCP:				Weight Lbs.		ions (US msr	•	Volume	Saleable #
Other exemption - Write in: Is product repackaged?			No		If you was a	riginal product purch	hased	Item/Each:		Depth	Width	Height	(Cube)	Pieces
Is product repackaged:	s exclusive distribut	tor?	Yes	-	direct from n		laseu	item/Lacii.	0.2	1.5	1.5	4	9	1
Has FDA granted waiver/exceptio			No	+			repackaged product	Box/Carton/Bu	undle/					
If yes, attach documentation from	m FDA.							Inner Pack:						
								Case:	5.3	9.5	6.5	5	308.75	24
		G.	FIN AND HIBCC PRODUCT IF	NFORMATION				Pallet:				-		
Saleable Unit of Measure	RFID tag(Y/N)	Salaabla	HIBCC		CT	IN-14	Unit of Use GTIN-14	Pallet:						
Saleable Offit of Measure	KFID (ay(1/N)	Quantity	ПВСС		Gi	IIN-14	Offit of Ose G1114-14							
x Item/Each	N	1 1			003	331722532013								
Box/Carton/Bundle/Inner Pack									COST INFORMATION			WHOLESAL	ER USE ONL	.Y:
X Case	N	24			203	331722532017								
Pallet								Regular Cost			Vendor #:			
								Invoice Cost (WAC) (\$)	\$45.00	Whsl. Code			
								As of date:	9/1/2009		Fineline Co	de:		
								AS OF Gale:	9/1/2009					
											-			
											1			
			Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza	ard letter, PACKAGE I	NSERT, LABEL AND PHOTO OF	PRODUCT PACKA	GING and BARCODE.					



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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? 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:						



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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: Drop Ship service fee billed: Drop Ship service fee billed with each order: Drop Ship service fee billed: Drop Ship ser	a. EDI		Cut off time:
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