

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

Version 2024							Introduction 1	Type:	New Item		x Fina	al Version			Date:	6/10/	2025
				PRODUCT INFORMAT	TION						\$	SPECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA						ANDA	a. Temperature – Indicate the USP temperature range for this product.										
Application Number for NDA/AN	DA/BLA; PMA/510	D(k):	216356				NDA 505(b) Type	:	NOT APPLICABLE	·	Temperature		Cold – between 2		– 46° F)		
Medical Device Class, if applicat	ble:																
DUNS:	11-856-3719										Other Tempe	rature Range F	Requirement				
Proprietary Name (If Applicable) a		ame:	Trientine Hyd	drochloride Capsules, I	JSP 250 mg						(write in	1)					
Selling Unit NDC:	31722-683-01			Unit of Use NDC:			UPC:	331722	683012		Notes			*To be shipped	to customers usi Cold Packs, Cold	ng proper cold st	torage shipping
UDI				CVX Code:			MVX Code:							mealous (e.g. c	Joid Facks, Cold		
Description:	Trientine Hydroch	hloride Capsule	es, USP 250 r	ng									d to customers on ic			No*	
Is this product to be shipped to customers on dry ice?																	
Active Ingredient(s): Trientine hydrochloride, USP b. Contact for temperature excursion questions:																	
URL for Additional Product Inform	nation:	www.camber	pharma.com							b. Contact to	Name:	excursion que	estions:	Soma Raju			
Address:	800 Centennial A		pridiriid.com				Address 2:				Number:			732-529-042	23		
City:	Piscataway					State:	State: NJ Zip: 08854			Group E-mail: somaraju@heterousa.com							
Key Contact:	Customer Service	е				Email:											
Phone Number:	1-866-827-3647					Fax:	732-562-8788			c. Special regulations for product in any states?				No			
Product Therapeutic Classification	n:	Copper chela	ator								Special return	ns requirement	ts for this product?			No	
	ADDITI	IONAL PRODU					PRODUCT	DESCRIF	PTION INFORMATION	d. Store prod	duct (unit of sa					No	
The product is?				the Product	Direct-Ship C	Only		_			Protect prod	uct (unit of sa	ale) from light?			No	
a legend device?		No		the Product	Neither		Size:		100 ct	e. Shelf life:	1	w	16 -1166			24	Months
if yes, enter class #		lat.	Or	phan Drug Status					050		Initial shelf l	ife at launch (i	if different):				Months
a product kit? if yes, list NDCs of		No	ED	A Approval Status			Strength:	1	250 mg				ORDER INFORM	ATION			
component parts			10	A Approvai Status				1	Hard gelatin capsule				ONDER IIII ONIII	,,,,,			
reverse numbered?		No					Dosage Form	m:	nara goldan bapoulo		Unit of Sale			What is the	NDC selling	unit?	
co-licensed?		No	All	lergens Present				_			x Bot	tle		1 Bottle of 1	00 Capsules		
latex-free?		Yes					Product Sha	ane.	Capsule		Box	/Carton		(Write-in, e.	g. 1 Box of 10) Vials)	
preservative-free?		Yes					1 Todact One				Am						
correctional institution block?		No					Product Col		Purple opaque cap and		Gla			Minimum or	rder quantity	?	Yes
opioid?		No			India				purple opaque body		Tub						
Cannabinoid? If Unit Dose, is item bar coded to u	init dose for	No	00	ountry of Origin	IIIula		Product Imp		Imprinted 'H' on cap and 'T4' on body in black ink			l Liquid Sgl I Liquid Multi		If Voe how	many of whi	ch nackago t	huno?
hospital scanning?	ariit dose ioi		ls t	this product covered u	nder the			L	TT OIL BODY III BIGOK IIIK			Powder Sal			Each	cii package i	type:
If Unit Dose, indicate NDC here:				ade Agreements Act (T		No						Powder Multi			Inner/Carton	/Pack	
											Oth	er: Write In			Case		
			FOR	GENERIC DRUG PRO	DDUCTS												
												DU	A DIMA OV ODDED	/ BULL LINUT			
					_	Au	thorized Generic		orized Generic, other fields are not applicable				IARMACY ORDER				
I. Orange Book Rating:	AB						section fields are not applicable			Rec. sell unit to customer? Rx billing unit to pharmacy:							
II. Generic Equivalent to What Brand?: Syprine						(Mrito in o.g. 1 Viol)					Each Gram						
(Write-in, e.g. 1 Vial) Gram DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION HCPCS J-Code: Milliliter																	
					,								1		,		
Does supplier meet DSCSA definit	ition of manufactu	irer?		Yes		GLN:	0843368117603					ITEN	AND PACKING IN	IFORMATIO	N		
Is product exempt from DSCSA?			No)													
If yes, select exemption:						GCP:					V	Weight Lbs.		ons (US msn		Volume	Saleable #
Other exemption - Write in:													Depth	Width	Height	(Cube)	Pieces
Is product repackaged?	ovelueise diet."	utor?	No	Yes	-	If yes, was or direct from m	riginal product pur	rchased		Item/Each:		0.17	1.97	1.97	3.98	15.45	1
Is product sold by manufacturer's Has FDA granted waiver/exception				No	+		ıır <i>r</i> ce manufacturer fo	or renach	raged product	Box/Carton/E	Bundle/						
If yes, attach documentation from		····		·-		Oriac soul	ooaiiaiaota/ei it	o. reputh	agoa product	Inner Pack:	-adio/						
										Case:		5.22	12.4	9	5.31	592.60	24
			GTIN AND	HIBCC PRODUCT IN	IFORMATION							J.22	12.4	9	3.31	332.00	24
Onlankin Half of Manager	DEID : 0/40									Pallet:							
Saleable Unit of Measure	RFID tag(Y/N)		HII	BCC		GTI	N-14		Unit of Use GTIN-14								
X Item/Each	N	Quantity 1				003	31722683012										
Box/Carton/Bundle/Inner Pack											COST IN	FORMATION			WHOLESALE	R USE ONL	Y:
X Case	N	24				203	31722683016										
Pallet										Regular Cost				Vendor #:			
										Invoice Cost	(WAC) (\$)		\$700.00	Whsl. Code			
								_		As of date:	2/4/	5/2023		Fineline Co	de:		
										As or date:	2/13	JI 2 U 2 J		1			
								_									
<u>'</u>			Attac	h copy of SAFETY DA	TA SHEET (SD	S) or non haza	rd letter, PACKAGE	E INSERT	, LABEL AND PHOTO OF P	RODUCT PACK	AGING and BA	RCODE.		•			
*Please provide any additional info	iormation on nago	. 2		.,	,02	,			ated Dron Shin Only		Signaturo						



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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? 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?	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	Hazardous Waste Identification							
e. Inhalation Hazard? Is this product regulated for shipment by IATA? No.	<u> </u>							
(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? 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: No Phone: DEA #: NCPDP#: NPI #:							
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	Comments							
SP#	Registry: No Registry Program Contact Name: Phone:							
ADD'L STORAGE INFORMATION Is the Product	Comments							
Controlled Substance? Controlled Substance? Controlled by State(s)? ARCOS Reportable? Schedule No. No If yes, indicate which: Is it a scheduled listed chemical product?: CLASS OF TRADE RESTRICTION:	Contact tel. # if product received damaged: 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:	Special regulations or returns requirements for this							
Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments)	product in certain states? If so, which states? Other requirements? Comments?							
Comments:								
MISCELL	ANEOUS 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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