

## **Standard Pharmaceutical Product Information (Rx Product Only)**

© August 2014 Post Launch Change Final Version Date: 5/2/2017																
			PRODUCT INFORMAT	ΓΙΟΝ							SPECIAL HANDL	ING AND STO	RAGE REQ	UIREMENTS	*	
Company Name:	Camber Pharmaceuti	cale				Applicat	tion:	ANDA	$\overline{}$	a. Temperature – Indica	to the USB temper	ratura rango	or this prod	uot		
Application Number for ND				204574		Арриса		711071			ure Range	ature range			en 20 and 25	5 C (68° – 77° F
		minoro(k)(med device)	•	201011						•	=		- COTTLI CHICA T	toom bottee	on to and to	70 (00 11 1
DUNS:	82-667-4775										nperature Range Re	quirement				7
Proprietary Name (If Applical		Name: Tetraben	azine 12.5MG 112CT							(wri	te in)					
Selling Unit NDC:	31722-821-11		Individual Unit NDC:	31722-821			17228211	17								
UDI			CVX Code:		M	VX Code:				Is this pro	duct to be shipped to	o customers o	n ice?		No	_
Description: White, flat bevel edged tablets embossed with H on lower punch at T5 on upper							Is this product to be shipped to customers on dry ice? No						_			
Active Ingredient(s):		Tetrabenazine								b. Contact for tempera	ure excursion que	stions:				
							Name:			Soma Raju						
	ditional Product Information: www.camberpharma.com						Number:			732-529-0423						
Address:	1031 Centennial Avenue Address 2:							Group E-mail: somaraju@heterousa.com								
City:	Piscataway Customer Service			State Emai		Zip: merservice@can		08854								
Key Contact: Phone Number:							nberpharma	a.com		c. Special regulations for product in any states?						
	732-529-0430 Fax: 732-562-8788					Special returns requirements for this product? No										
Product Therapeutic Classifi	ication:															
4 5 5 100 100 100 100 100 100 100 100 100			i							d. Store product (unit o					No	_
ADDITIONA	AL PRODUCT INFORM	ATION			PRODUC	CT DESCRIPTIO	N INFORM	IATION		Protect product (unit of sale) from light?  No					=	
Is the Product										e. Shelf life: 24 Mon					Months	
a legend device?		No	Size:			112	112			Initial shelf life at launch (if different):			M		Months	
reverse numbered?		No		OLC.		. 12										
co-licensed?		No		Strength:		12.5 mg					(	ORDER INFO	RMATION			
Is the Product		Direct-Ship Only		oog		12.0 mg										
Is the Product		Unit of Use		Dosage F	orm:	Oral solid table	et			Unit of S				NDC selling	unit?	
				-							Bottle		1 box of 12		0.16-1-1	
If Unit Dose, is item bar code	ed to unit dose for hosp	ital scanning?							<del></del>	x	Box/Carton		(vvrite-in, e	.g. 1 Box of 1	u viais)	
If Unit Dose NDC, indicate N	DC h			Product S	hape:	round					Ampule Glass			rder quantity		Yes
II Unit Dose NDC, indicate Ni	DC nere:								-		Tube		wiinimum o	raer quantity	11	res
Country of Origin		India		Product C	olor:	white					Vial Liquid Sgl					
										Vial Liquid Multi If Yes, how many of which package type?						
Is this product covered under the Trade Agreements Act (TAA)? No Product Imprint: white						Vial Powder Sql Each										
											Vial Power Multi			Inner/Cartor	/Pack	
			ı								Other: Write In		24	Case		
			FOR GENERIC DRUG PR	ODUCTS										_		
				<i>H</i>	Authorized Ge			Generic, other section	ion		PHAF	RMACY ORDE	R / BILL UNI	IT		
I. Orange Book Rating:	AB					fie	lds are not	applicable		Rec. sell unit to customer? Rx billing unit to pharmacy:						
II. Generic Equivalent to Wha	at Brand?:	Xenaxine								Each						
						(Write-in, e.g. 1 Vial)										
		DRUG SUPPI	Y CHAIN SECURITY ACT (	DSCSA) INFORMATION										Milliliter		
			V								ITEM A	ND DAOKING	INFORMATI	ION		
Does supplier meet DSCSA of Is product exempt from DSC			Yes No	GLN:							IIEMA	IND PACKING	INFORMATI	ON		
If yes, select exemption:	3A?		INU									Dimo	sions (US m	nemte \	Volume	
Other exemption - Write in:											Weight Lbs.	Depth	Height	Width	(Cube)	# Pieces:
Is product repackaged?	•		No	If Yes was or	iginal produ	ct purchased d	irect			Item:		Берии			(0000)	
Is product repackaged:	turer's exclusive distr		No	from mfr?	o produ	pa. onuocu u					0.1		3	1.5		
Has FDA granted waiver/exc			No	If ves. attach	documentat	tion from FDA.				Box/Carton/Bundle/						
		-		J						Inner Pack:						
			GTIN PRODUCT INFORM	MATION	_					Case:	2.45	10	4.5	6.5	0.169	24
			;	Saleable							2.45	10	4.5	0.5	0.109	24
			Level	Unit		Qu		GTIN-14		Pallet:						1396
Serialized?	Yes	х	Item	<b>x</b> 21		Linear	1	00331722821117								1000
If not, when?			Box/Carton/Bundle/Inner Pack	21		Linear				UPC:	Case:					
Items aggregated?	Yes	х	Case	<b>x x</b> 21			24	20331722821111			Carton:					
			Pallet	21		Linear				0007	NEODMATION			WUOL FOAT	ED HOE ON	
				21		Linear	<u> </u>			COST	INFORMATION			WHOLESAI	ER USE ON	F1;
		-				_			-	Damilar Cast			V			
		<u> </u>		21		Linear				Regular Cost		\$2.672.00	Vendor #: Whsl. Code	. #-		
11				21	· L	Lilibai			<b>-</b>	Invoice Cost (WAC) (\$) Federal Excise Tax Per		\$3,673.88	Fineline Co			
										As of date:	Onn Of Sale	1	i memie Co	uc.		
										, is or date.						
			Attach copy of SAFETY DA	TA SHEET (SDS) or not	hazard lette	or DACKAGE IN	SEDT I AD	EL AND PHOTO OF		THE BACKAGING 224 BA	PCODE					
*Please provide any addition	al information on no	10.2	ALLOUIN COPY OF SAFETY DE	TITLE (SDS) OF NO		er, PACKAGE IN: new p. 3 for Desi			FROD	Signatur						



## **Standard Pharmaceutical Product Information (Page 2)**

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL I	HAZARD CLASSIFICATION and TRANSPORTATION							
Is this product (check all that apply):								
a. Cytotoxic?	SDS Hazard Classification							
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	CDO Hazara Glassinoation							
Is the product a CA Prop 65 carcinogen?	Organic Corrosive							
Is the product a CA Prop 65 carcinogen?	Inorganic Oxidizer							
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard							
a Contact Harand?	A grand Class Identify NEDA Starges Levels							
c. Contact Hazard?	Aerosol Class; Identify NFPA Storage Level:							
d. Does this product require special clean-up instructions?  No	1.4. 1.4. 1100111							
(If yes, attach SDS with special instructions.)	Is the product a NIOSH hazardous drug?							
e. Does the product contain DEHP?	If yes, indicate which:							
Is this product regulated for shipment by DOT or IATA?  No								
(if yes, answer a-e below and provide SDS)								
a. UN/Identification Number								
b. Proper Shipping Name	Hazardous Waste Identification							
c. DOT Hazard Class	EPA Hazardous Waste Code: NA							
d. Packing Group								
e. Inhalation Hazard?								
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS							
Passenger	Is there a REMS on this product?							
Cargo	If Yes, is it managed with a pharmacy registry?							
Passenger & Cargo	Website URL:							
	Website ORL.							
Is this a reportable quantity? No								
RQ Threshold:	Comments / Details: (For example, iPledge program?)							
Is this a marine pollutant? No	None							
Is this product shipped utilizing an authorized DOT exception or Special Permit?								
No (if yes, identify method below)	REMS: Yes							
Limited Quantity	REMS Program Manager Name:	Phone:						
Consumer Commodity, ORM-D	Supplier Manages REMS registry exclusively: No							
Small Quantity (49 CFR 173.4)	Wholesale distributor support: No							
Special Permit; DOT-SP	Provider Name:							
Special Provision (listed in Column 7 of 49 CFR 172.101);	Site Enrollment Number assigned	DEA #: No						
SP#	by Supplier:	PCPDP #: No						
		NPI#: No						
ADD'L STORAGE INFORMATION								
Is the Product	Comments None							
Controlled Substance? No								
Controlled by State(s)?	Registry: No							
ARCOS Reportable? No	Registry Program Contact Name:	Phone:						
Schedule No. (inc. N for non-narcotic)	Comments							
Controlled Substance Code								
Listed Chemical (List I or II) No	RETURN INSTRUCTIONS							
If yes, indicate which:								
Is it a scheduled listed chemical product?:  No	Contact tel. # if product received damaged: 732-529-0430							
CLASS OF TRADE RESTRICTION:	Is product returnable for credit:							
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	URL/Link to returns policy: contact - customerservice@ca	ombornbormo com						
		,						
Restricted to retail pharmacy only: Yes	Special regulations or returns requirements for this product in certain states?	No						
Restricted to hospital, clinics, and physician offices only:	If so, which states? Other requirements? Comments?							
Restricted from US territories? (explain in comments)  No								
Comments:								
Comments.								
MISCELLAR	NEOUS NOTES and/or Image of Product Barcode:							



## **Standard Pharmaceutical Product Information (Page 3)**

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  Yes  No Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time: 2:30PM Eastern						
c. Fax  d. Phone only  No Phone No.:	Shipping lead time of PO: 24/48 Hours Days						
e. Supplier Web Site only No Site Address:	Ships same day for next day receipt: No						
Minimum Order Quantity: case pack	Ships for second day receipt:  No						
Supplier's Customer Service Number: 732-529-0430 x466 x465 x467 x470	Ships regular ground for 3-10 days receipt:  Yes						
Contracted 3PL company / contact #: Name: Phone:							
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing						
Expedited freight fees billed with each order: No No	Overnight receipt available: Yes						
Drop Ship service fee billed with each order: No No	PO Receipt cut off time: 2:30PM Eastern						
Drop Ship miscellaneous fees billed: No	Days of week overnight is available:						
Comments:	x Tuesday x Wednesday Thursday x Friday						
	Priority Overnight receipt available: Yes						
Class of Trade Restriction:	PO Receipt Cut off time: 2:30PM EST						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No	Saturday Overnight receipt available: No						
Restricted to retail pharmacy only:  Yes	PO Receipt Cut off time:						
Restricted to hospital, clinics, and physician offices only:  No	Order receipt method:  No Phone #:						
Restricted from US territories? (explain in comments)  No	Fax: Yes Fax #: 732-562-8788						
Comments:	EDI: Yes						
	Overnight Fees apply:  Other fees apply:  No						
Other Data Information Demoired to Decree DO							
Other Data Information Required to Process PO:	Return Instructions						
Patient Procedure Date:  Physician Name:	Contact # if product is received damaged:  Is product returnable for credit:  Yes						
Physician/Clinic Phone #	URL/Link to returns policy:						
Physician State License #	Special regulations or returns requirements for this product in certain states?  Yes						
Physician/Clinic DEA #:	If so, which states? Other requirements? Comments?						
Physician/Clinic Specialty:	·						
Miscellaneous Notes:							
	ADDITIONAL INFORMATION						
	Is product order for scheduled patient procedure?						
	Is product order for restocking purposes?						