

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

Version 2024						Introduction Type	: New Item	X	Final Version			Date:	3/17/	/2025
			PRODUCT INFORMAT	ION					SPECIAL HAN	DLING AND STOR	AGE REQUIF	EMENTS*		
Company Name:	Camber Pharmac	euticals. Inc.				Application	ANDA	a. Temperature – Indica	ate the USP tempe	rature range for th	is product.			
Application Number for NDA/AND	DA/BLA: PMA/510	(k): 218110				NDA 505(b) Type:	NOT APPLICABLE		ture Range	Controlled Room -		and 25 C (68°	– 77° F)	
Medical Device Class, if applicab						,,,,,		T I	5					
DUNS:	11-856-3719							Other Te	mperature Range F	Requirement	Excursions p	ermitted to 15	5°C to 30°C (	59°F to
Proprietary Name (If Applicable) ar	nd Established Na	me: Phenyle	phrine Hydrochloride Injecti	ion, USP 50 mg	/5 mL (10 mg/n	L) Pharmacy Bulk Pac	kages		ite in)		86°F)			
	31722-344-31		Unit of Use NDC:		31722-344-05		1722344319	Notes	,					
UDI			CVX Code:			MVX Code:		Ť						
Description:	Phenylenhrine Hy	drochloride Injection I	JSP 50 mg/5 mL (10 mg/mL	) Pharmacy Rul	k Packanes			le this no	nduct to be shinned	to customers on ic	62		No	
Description.	1 Herry reprinted try	arounionae injection, e	or or mg/o me (ro mg/me	, i namacy bu	K i dokages					to customers on d			No	
Active Ingredient(s):		Phenylephrine hydrod	chloride, USP								,	l.		1
5 ,,		, , ,						b. Contact for temperar	ture excursion que	estions:				
URL for Additional Product Informa	ation:	www.camberpharma.	com					Name:			Soma Raju			
Address:	800 Centennial A	ve, Suite 1				Address 2:		Number			732-529-042			
City:	Piscataway							Group E-mail: somaraju@heterousa.com						
Key Contact:	Customer Service	•			Email:	customerservice@ca	mberpharma.com						1	
Phone Number:	1-866-827-3647	1			Fax:	732-562-8788		c. Special regulations f	-				No	
Product Therapeutic Classification	1:	Alpha-1 adrenergic re	eceptor agonist					Special r	eturns requirement	s for this product?			No	1
														1
	ADDIII	ONAL PRODUCT INFO				PRODUCT DES	CRIPTION INFORMATION	d. Store product (unit of				ļ	No	1
The product is?			Is the Product	Direct-Ship O	nly				product (unit of sa	le) from light?			No	
a legend device?		No	Is the Product	Unit of Use		Size:	10 x 5 mL pharmacy bulk	e. Shelf life:					24	Months
if yes, enter class #		1	Orphan Drug Status				package vials	Initial sh	elf life at launch (i	if different):				Months
a product kit?		No				Strength:	50 mg/5 mL (10 mg/mL)		ORDER INFORMATION					
if yes, list NDCs of component parts			FDA Approval Status				Cterile alees selution			ORDER INFORM	ATION			
reverse numbered?		No				Dosage Form:	Sterile, clear solution	Unit of S	ala		What is the	NDC selling	ınit?	
co-licensed?		No	Allergens Present						Bottle		1 Box of 10 >			ckane Vials
latex-free?		Yes	7 mor gono i rocom				N/A	x	Box/Carton			. 1 Box of 10		mago viaio
preservative-free?		Yes				Product Shape:			Ampule		, , , ,	,	,	
correctional institution block?		No				Product Color:	Colorless	x	Glass		Minimum or	der quantity	?	Yes
opioid?		No				Froduct Color.			Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint:	N/A		Vial Liquid Sgl					
If Unit Dose, is item bar coded to un	nit dose for					oddot imprint		x	Vial Liquid Multi		If Yes, how		h package t	type?
hospital scanning?			Is this product covered ur						Vial Powder Sgl			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (T.	AA)?	No				Vial Powder Multi			Inner/Carton/	Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PRO	DDUCTS										
							Authorized Conseils of the		DU	ARMACY ORDER	/ DILL LIMIT			
				_	Au		Authorized Generic, other ction fields are not applicable			ARWACT ORDER				
	AP					36	ction fields are not applicable	Rec. sell unit to custon	ner?	1	Rx billing ur		су:	
II. Generic Equivalent to What Bran	nd?:	Vazculep						04/-11-1				Each		
		DRUG SUPPLY	CHAIN SECURITY ACT (	OSCSA) INFOR	MATION			(Write-in, e.g. 1 Vial)  HCPCS J-Code:				Gram Milliliter		
		DROG GOLLE	OTATI DE CONTINUE (E	occa, in on	MATION			J2371		1		wiiiiiitei		
Does supplier meet DSCSA definit	tion of manufactur	er?	Yes	П	GLN:	0331722498975		02011		AND PACKING IN	FORMATION			
Is product exempt from DSCSA?			No											
If yes, select exemption:					GCP:			1		Dimensio	ons (US msm	te \	Volume	Saleable #
Other exemption - Write in:					GOF.				Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If ves. was or	ginal product purchas	sed	Item/Each:						
Is product sold by manufacturer's			.,,	-	direct from m				0.44	5.2	2	2.6	27.04	1
	exclusive distribu	itor?	Yes											
Has FDA granted waiver/exception			Yes No		Provide source	e manufacturer for re	packaged product	Box/Carton/Bundle/						
Has FDA granted waiver/exception If yes, attach documentation from	n/exemption for pr				Provide source		packaged product	Box/Carton/Bundle/ Inner Pack:					786.5	20
	n/exemption for pr	oduct?	No		Provide source		packaged product		10.05	11	11	6.5		
	n/exemption for pr	oduct?		IFORMATION	Provide source		packaged product	Inner Pack: Case:	10.05	11	11	6.5		
If yes, attach documentation from	n/exemption for pr n FDA.	oduct?	No AND HIBCC PRODUCT IN	IFORMATION		e manufacturer for re		Inner Pack:	10.05	11	11	6.5		
	n/exemption for pr	GTIN Saleable	No	IFORMATION	Provide source	e manufacturer for re	Dackaged product Unit of Use GTIN-14	Inner Pack: Case:	10.05	11	11	6.5		
If yes, attach documentation from	n/exemption for pr n FDA. RFID tag(Y/N)	GTIN Saleable Quantity	No AND HIBCC PRODUCT IN	IFORMATION	GTII	e manufacturer for re	Unit of Use GTIN-14	Inner Pack: Case:	10.05	11	11	6.5		
If yes, attach documentation from Saleable Unit of Measure  x   tem/Each	n/exemption for pr n FDA.	GTIN Saleable	No AND HIBCC PRODUCT IN	IFORMATION	GTII	e manufacturer for re		Inner Pack: Case: Pallet:		11				Y:
Saleable Unit of Measure    X	n/exemption for pr n FDA. RFID tag(Y/N)	GTIN Saleable Quantity	No AND HIBCC PRODUCT IN	IFORMATION	GTII	e manufacturer for re	Unit of Use GTIN-14	Inner Pack: Case: Pallet:	10.05	11		6.5 WHOLESALE		Y:
Saleable Unit of Measure    X	n/exemption for pr n FDA.  RFID tag(Y/N)	GTIN Saleable Quantity 1	No AND HIBCC PRODUCT IN	IFORMATION	GTII	N-14	Unit of Use GTIN-14	Inner Pack: Case: Pallet:  cos			Vendor #:	VHOLESALE		Y:
Saleable Unit of Measure  X     tem/Each	n/exemption for pr n FDA.  RFID tag(Y/N)	GTIN Saleable Quantity 1	No AND HIBCC PRODUCT IN	IFORMATION	GTII	N-14	Unit of Use GTIN-14	Inner Pack: Case: Pallet:			Vendor #: Whsl. Code	VHOLESALE		Y:
Saleable Unit of Measure  X     tem/Each	n/exemption for pr n FDA.  RFID tag(Y/N)	GTIN Saleable Quantity 1	No AND HIBCC PRODUCT IN	IFORMATION	GTII	N-14	Unit of Use GTIN-14	Inner Pack: Case: Pallet:  COS  Regular Cost Invoice Cost (WAC) (\$)	TINFORMATION		Vendor #:	VHOLESALE		Y:
Saleable Unit of Measure  X     tem/Each	n/exemption for pr n FDA.  RFID tag(Y/N)	GTIN Saleable Quantity 1	No AND HIBCC PRODUCT IN	IFORMATION	GTII	N-14	Unit of Use GTIN-14	Inner Pack: Case: Pallet:  COS  Regular Cost Invoice Cost (WAC) (\$)			Vendor #: Whsl. Code	VHOLESALE		Y:
Saleable Unit of Measure  X     tem/Each	n/exemption for pr n FDA.  RFID tag(Y/N)	GTIN Saleable Quantity 1	No AND HIBCC PRODUCT IN	IFORMATION	GTII	N-14	Unit of Use GTIN-14	Inner Pack: Case: Pallet:  COS  Regular Cost Invoice Cost (WAC) (\$)	TINFORMATION		Vendor #: Whsl. Code	VHOLESALE		Y:
Saleable Unit of Measure  X     tem/Each	n/exemption for pr n FDA.  RFID tag(Y/N)	GTIN Saleable Quantity 1 20	No AND HIBCC PRODUCT IN HIBCC		GTII 003: 203:	N-14 31722344319 31722344313	Unit of Use GTIN-14 00331722344319	Inner Pack: Case: Pallet:  Cos Regular Cost Invoice Cost (WAC) (\$) As of date:	T INFORMATION 3/11/2025		Vendor #: Whsl. Code	VHOLESALE		Y:
Saleable Unit of Measure  X     tem/Each	Nexemption for prin FDA.  RFID tag(Y/N)  N  N	GTIN Saleable Quantity 1 20	No AND HIBCC PRODUCT IN HIBCC		GTII 003: 203:	N-14 81722344319 81722344313	Unit of Use GTIN-14	Inner Pack: Case: Pallet:  Cos Regular Cost Invoice Cost (WAC) (\$) As of date:	TINFORMATION 3/11/2025 BARCODE.		Vendor #: Whsl. Code	VHOLESALE		Y:



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

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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?	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					
ls this product regulated for shipment by IATA?	EFA Hazaiuous 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: No Phone:  DEA #: NCPDP#: NCPDP#: NPI #:					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments  Registry:  No					
	Registry Program Contact Name: Phone:					
ADD'L STORAGE INFORMATION	Comments					
Is the Product  Controlled Substance?  Controlled Substance Code  Controlled by State(s)?  ARCOS Reportable?  Schedule No.  No  Controlled Substance Code  Listed Chemical (List I or II)  No  If yes, indicate which:  Is it a scheduled listed chemical product?:  No	RETURN INSTRUCTIONS  Contact tel. # if product received damaged:  Is product returnable for credit:  Yes					
CLASS OF TRADE RESTRICTION:	URL/Link to returns policy:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes	contact - customerservice@camberpharma.com					
Restricted to retail pharmacy only:  Restricted to hospital, clinics, and physician offices only:  No Restricted from US territories? (explain in comments)  No	Special regulations or returns requirements for this product in certain states?  If so, which states? Other requirements? Comments?					
Comments:						
MISCELLAN	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.

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