

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

Version 2021					Introduction Type: Post Launch Change] [x Final Version			Date:	8/12/	2025		
			PRODUCT INFORMAT	ION						SPECIAL HAND	LING AND STOR	AGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc.				Application: ANDA			a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 040901									Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)						
Medical Device Class, if applical			·							,					
DUNS:	11-856-3719								'	Other Temperature Range F	Requirement				
Proprietary Name (If Applicable) a	and Established Na	me: Hydra	lazine Hydrochloride Tablets	USP 10 mg					1	(write in)					
Selling Unit NDC:	31722-519-01		Unit of Use NDC:			UPC:	331722	2519014]	Notes					
UDI			CVX Code:			MVX Code:									
Description:	Hydralazine Hydrod	chloride Tablets, US	SP 10 mg]	s this product to be shipped	to customers on	ce?		No	
, , , , , , , , , , , , , , , , , , , ,								s this product to be shipped	to customers on	dry ice?		No			
Active Ingredient(s): Hydralazine hydrochloride, USP															
							b. Contact for temperature excursion questions:								
URL for Additional Product Inforr		www.camberpharn	ma.com							Name:		Soma Raju			
Address:	800 Centennial Ave				Ctata	Address 2: NJ Zip: 08854			Number: 732-529-0423 Group E-mail: somaraju@heteror				IOO COM		
City: Key Contact:	Piscataway Customer Service		State:						Group E-mail:			<u>somaraju@r</u>	ieterousa.coi	<u>n</u>	
Phone Number:	1-866-827-3647		Email:		Fax:	customerservice@camberpharma.com 732-562-8788		c Special requi	lations for product in any	etatoe?			No		
Product Therapeutic Classification		Vasodilator			ı ux.	732-302-6766				Special returns requirements				No	
Froduct Therapeutic Classificatio)II.	Vasoulialoi							1	Special returns requirement	s for this product?			INO	
	ADDITIO	NAL PRODUCT IN	IFORMATION			PRODUCT	DESCRI	PTION INFORMATION	d Store produc	ct (unit of sale) upright?				No	
The mandered in O	7.550		Is the Product	Direct-Ship O	um la c	T NODGO!			11	· · · · -	I-) f !!b40			No	
The product is? a legend device?		No	is the Product	Neither	TIIY			100 ct	e. Shelf life:	Protect product (unit of sa	ie) from light?			24	Months
if yes, enter class #		INO	Orphan Drug Status	IVEILLIEI		Size:		100 Ct		nitial shelf life at launch (i	f different):			24	Months
a product kit?		No	Orphun Drug Otatus				-	10 mg		initial Shell life at launen (i	r amerenty.				Worthis
if yes, list NDCs of		.,,	FDA Approval Status			Strength:					ORDER INFORM	MATION			
component parts						Dosage For		Tablet							
reverse numbered?		No				Dosage For	m:		l l	Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present							x Bottle		1 Bottle of 1	00 Tablets		
latex-free?		Yes				Product Sha	ape:	Round		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes								Ampule				_	
correctional institution block?		No				Product Co	lor:	Orange		Glass		Minimum o	rder quantity	y?	Yes
opioid? Cannabinoid?		No No	Country of Origin	India				Unscored, debossed with 'H' on one	-	Tube Vial Liquid Sgl					
If Unit Dose, is item bar coded to u		NO	Country of Origin	iriuia		Product Imp	print:	side and '38' on the other side		Vial Liquid Sgi		If Voe how	many of wh	ich package	typo?
hospital scanning?	uniit dose ioi		Is this product covered u	nder the			l.			Vial Powder Sgl			Each	icii packaye	type:
If Unit Dose, indicate NDC here:			Trade Agreements Act (1		No					Vial Powder Multi			Inner/Cartor	/Pack	
If Utilit Dose, Indicate NDC fiere.									Other: Write In			Case	ar don		
			FOR GENERIC DRUG PRO	DUCTS											
												_			
					Au	thorized Generic	*If Auth	norized Generic, other	PHARMACY ORDER / BILL UNIT						
I. Orange Book Rating:	AA					section fields are not applicable			Rec. sell unit to customer? Rx billing unit to pha			nit to pharm	macv:		
II. Generic Equivalent to What Brand?: Hydralazine Hydrochloride (Pliva) - RS			_							Each					
-	'	•							(Write-in, e.g. 1	Vial)			Gram		
		DRUG SUPPL	Y CHAIN SECURITY ACT (I	SCSA) INFOR	MATION								Milliliter		
				_											
Does supplier meet DSCSA defini		er?	Yes No	_	GLN:	0331722498975				ITEM	AND PACKING II	NFORMATION			
Is product exempt from DSCSA?			INO						!						
If yes, select exemption:					GCP:]	Weight Lbs.		ons (US msn	•	Volume	Saleable #
Other exemption - Write in:											Depth	Width	Height	(Cube)	Pieces
Is product repackaged?	a avaluabre distori	10 m	No			iginal product			Item/Each:	0.05	1.5	1.5	3	6.75	1
Is product sold by manufacturer's Has FDA granted waiver/exceptio			Yes No	-		rect from mfr? ce manufacturer f	for ronce	kaged product	Box/Carton/Bu	ndle/					
If yes, attach documentation fro		oduct r	140		FIOVICE Soul	ce manuracturer i	ioi repac	kageu product	Inner Pack:	nule/					
you, attaon accumontation no									Case:						
				FORMATION					1	1.6	9.5	6.5	4	247	24
		GTI	N AND HIBCC PRODUCT IN												
		GTII	N AND HIBCC PRODUCT IN	TORMATION					Pallet:						
Saleable Unit of Measure	Sa	GTII	N AND HIBCC PRODUCT IN	- Ortination	GTII	N-14		Unit of Use GTIN-14	Pallet:						
X Item/Each	Sa			ORMATION		N-14 31722519014		Unit of Use GTIN-14	Pallet:						
X Item/Each Box/Carton/Bundle/Inner Pack	Sa	leable Quantity			0033	31722519014		Unit of Use GTIN-14	Pallet:	COST INFORMATION		\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	WHOLESAL	ER USE ONL	.Y:
X Item/Each Box/Carton/Bundle/Inner Pack X Case	Sa				0033			Unit of Use GTIN-14		COST INFORMATION			WHOLESAL	ER USE ONL	Y:
X Item/Each Box/Carton/Bundle/Inner Pack	Sa	leable Quantity			0033	31722519014		Unit of Use GTIN-14	Regular Cost			Vendor #:		ER USE ONL	Y:
X Item/Each Box/Carton/Bundle/Inner Pack X Case	Sa	leable Quantity			0033	31722519014		Unit of Use GTIN-14			\$4.43	Vendor #: Whsl. Code	#:	ER USE ONL	Y:
X Item/Each Box/Carton/Bundle/Inner Pack X Case	Sa	leable Quantity			0033	31722519014		Unit of Use GTIN-14	Regular Cost Invoice Cost (V	VAC) (\$)	\$4.43	Vendor #:	#:	ER USE ONL	Y:
X Item/Each Box/Carton/Bundle/Inner Pack X Case	Sa	leable Quantity			0033	31722519014		Unit of Use GTIN-14	Regular Cost		\$4.43	Vendor #: Whsl. Code	#:	ER USE ONL	Y:
X Item/Each Box/Carton/Bundle/Inner Pack X Case	Sa	leable Quantity			0033	31722519014		Unit of Use GTIN-14	Regular Cost Invoice Cost (V	VAC) (\$)	\$4.43	Vendor #: Whsl. Code	#:	ER USE ONL	Y:
X Item/Each Box/Carton/Bundle/Inner Pack X Case	Sa	lleable Quantity 1 24			2033	31722519014	INSERT		Regular Cost Invoice Cost (V	4/15/2024	\$4.43	Vendor #: Whsl. Code	#:	ER USE ONL	Y:



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

Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MA	TERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION				
Is this product (check all that apply):						
a. Cytotoxic?	SDS Hazard Classification					
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?						
Is the product a CA Prop 65 carcinogen?	x Organic	Corrosive				
Is the product a CA Prop 65 reproductive toxicant?	No No	Inorganic	Oxidizer			
Does the product label bear a CA Prop 65 warning?	No	Steroid/Androgen	Contact Hazard			
bood the product labor boar a over rop to warming.	140	Citation and and an analysis of the citation and an analysis o	_ Contact Hazard			
c. Contact Hazard?	No	Does the product have an Aerosol class? If yes,	No			
d. Does this product require special clean-up instructions?	No	identify NFPA Storage Level:	110			
(If yes, attach SDS with special instructions.)	140	NFPA Storage Level:				
e. Does the product contain DEHP?	No	141 77 Glorago Edvol.				
*						
Is this product regulated for shipment by DOT?	No	Is the product a NIOSH hazardous drug?	No			
(if yes, answer a-e below and provide SDS)		If yes, indicate which:				
a. UN/Identification Number						
b. Proper Shipping Name						
c. DOT Hazard Class	Hazardous Waste Identification					
d. Packing Group						
e. Inhalation Hazard?		EPA Hazardous Waste Code:		Waste Characteristics		
Is this product regulated for shipment by IATA?	No					
(if yes, answer a-e below and provide SDS)		REMS or	REGISTRY RESTRICTIONS			
a. UN/Identification Number						
b. Proper Shipping Name		Is there a REMS on this product?	No			
c. DOT Hazard Class		If Yes, is it managed with a pharmacy registry?				
d. Packing Group		Website URL:				
e. Inhalation Hazard?						
Is the product restricted for air shipment? If so, indicate restriction:	No	Med Guide Required	No			
Passenger		Limited Distribution Requirement				
Cargo		Comments / Details: (For example, iPledge program?)				
Passenger & Cargo						
Is this a reportable quantity? No		REMS:	No			
RQ Threshold:		REMS Program Manager Name:	NO	Phone:		
Is this a marine pollutant? No		Supplier Manages REMS registry exclusively:		T Hone.		
Is this product shipped utilizing an authorized DOT exception or Special Permit?	Wholesale distributor support:					
No (if yes, identify method below)		Provider Name:		DEA#:		
Limited Quantity		Site Enrollment Number assigned		NCPDP#:		
Consumer Commodity, ORM-D		by Supplier:		NPI #:		
Small Quantity (49 CFR 173.4)		э, саррион				
Special Permit; DOT-SP		Comments				
Special Provision (listed in Column 7 of 49 CFR 172.101);		Commente				
SP#		Registry:	No			
		Registry Program Contact Name:		Phone:		
ADD'L STORAGE INFORMATION		Comments		i none.		
		Comments				
Is the Product			TURN INOTRUCTIONS			
Controlled Substance? No Controlled Substance Code		RE	ETURN INSTRUCTIONS			
Controlled by State(s)? No Listed Chemical (List I or II)	No		1 000 007 0047			
ARCOS Reportable? No If yes, indicate which:		Contact tel. # if product received damaged:	1-866-827-3647			
Schedule No. Is it a scheduled listed chemical product?:	No	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 - customerse	ervice@camberpharma.com			
	No		<u> </u>			
Restricted to retail pharmacy only:	Special regulations or returns requirements for this					
Restricted to hospital, clinics, and physician offices only:	product in certain states?	No				
Restricted from US territories? (explain in comments)	No	If so, which states? Other requirements? Comments?				
Comments:						
	0051	NUO NOTEO d/ lus (-D				
MI	SCELLANE	OUS NOTES and/or Image of Product Barcode:				



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

Version 2021

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:	Purchase order daily receipt cut off time by supplier
a. EDI	Cut off time:
b. Autofax Fax Number:	
c. Fax Number:	Shipping lead time of PO: Hours Days
d. Phone No.:	
e. Supplier Web Site only Site Address:	Ships same day for next day receipt:
Minimum Order Quantity:	Ships for second day receipt:
Supplier's Customer Service Number: Contracted 3PL company / contact #: Name:	Ships regular ground for 3-10 days receipt:
Phone:	
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:	Days of week overnight is available: Monday
Comments:	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 office	es Saturday Overnight receipt available:
Restricted to retail pharmacy only:	PO Receipt Cut off time:
Restricted to hospital, clinics, and physician offices only:	Order receipt method: Phone: Phone #:
Restricted from US territories? (explain in comments)	Fax: Fax#:
Comments:	EDI:
	Overnight Fees apply:
	Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	Contact # if product is received damaged:
Physician Name:	Is product returnable for credit:
Physician/Clinic Phone #	URL/Link to returns policy:
Physician State License # Physician/Clinic DEA #:	Special regulations or returns requirements for this product in certain states?
Physician/Clinic Specialty:	If so, which states? Other requirements? Comments?
Miscellaneous Notes:	il se, which etates. Other requirements.
Wiscellaneous Notes.	
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure?
	Is product order for restocking purposes?