



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

Version 2024

Introduction Type: New Item

☒ Final Version

Date: 8/12/2025

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: Camber Pharmaceuticals, Inc.				Application: ANDA			
Application Number for NDA/ANDA/BLA; PMA/510(k): 040901				NDA 505(b) Type: NOT APPLICABLE			
Medical Device Class, if applicable:							
DUNS: 11-856-3719							
Proprietary Name (If Applicable) and Established Name: Hydralazine Hydrochloride Tablets, USP 100 mg							
Selling Unit NDC: 31722-522-05				Unit of Use NDC:			
UDI				UPC: 331722522052			
CVX Code:				MVX Code:			
Description: Hydralazine Hydrochloride Tablets, USP 100 mg							
Active Ingredient(s): Hydralazine hydrochloride, USP							
URL for Additional Product Information: www.camberpharma.com							
Address: 800 Centennial Ave, Suite 1				Address 2:			
City: Piscataway				State: NJ			
Key Contact: Customer Service				Zip: 08854			
Phone Number: 1-866-827-3647				Email: customerservice@camberpharma.com			
Product Therapeutic Classification: Vasodilator				Fax: 732-562-8788			
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is?		Is the Product...		Size:		500 ct	
a legend device?		Is the Product...		Strength:		100 mg	
if yes, enter class #		Orphan Drug Status		Dosage Form:		Tablet	
a product kit?				Product Shape:		Round	
if yes, list NDCs of component parts		FDA Approval Status		Product Color:		Orange	
reverse numbered?				Product Imprint:		Unscored, debossed with 'H' one one side and '41' on the other side	
co-licensed?		Allergens Present					
latex-free?							
preservative-free?		Country of Origin		India			
correctional institution block?							
opioid?							
Cannabinoid?							
If Unit Dose, is item bar coded to unit dose for hospital scanning?		Is this product covered under the Trade Agreements Act (TAA)?		No			
If Unit Dose, indicate NDC here:							
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating: AA				☐ Authorized Generic *If Authorized Generic, other section fields are not applicable			
II. Generic Equivalent to What Brand?: Hydralazine Hydrochloride (Pliva)							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer?		Yes		GLN:		0331722498975	
Is product exempt from DSCSA?		No		GCP:			
If yes, select exemption:				If yes, was original product purchased direct from mfr?		No	
Other exemption - Write in:				Provide source manufacturer for repackaged product			
Is product sold by manufacturer's exclusive distributor?		No					
Has FDA granted waiver/exception/exemption for product?		No					
If yes, attach documentation from FDA.							
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure		RFID tag(Y/N)		Saleable Quantity		HIBCC	
Item/Each		N		1		GTIN-14	
Box/ Carton/ Bundle/ Inner Pack		N		12		00331722522052	
Case		N		12		20331722522056	
Pallet							
ITEM AND PACKING INFORMATION							
Weight Lbs.		Dimensions (US msmts.)		Volume (Cube)		Saleable # Pieces	
Depth		Width		Height			
Item/Each:		0.7		3		5.75	
Box/ Carton/ Bundle/ Inner Pack:		12.75		9.75		6.5	
Case:		9.2		12.75		808.03	
Pallet:							
COST INFORMATION				WHOLESALE USE ONLY:			
Regular Cost		Invoice Cost (WAC) (\$)		Vendor #:			
As of date:		12/4/2024		Whsl. Code #:			
		\$71.05		Fineline Code:			

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature:



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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?
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?

- 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?

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
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?

Is this product regulated for shipment by IATA?
(if yes, answer a-e below and provide SDS)

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?

Is the product restricted for air shipment? If so, indicate restriction:

- ☐ Passenger
- ☐ Cargo
- ☐ Passenger & Cargo

Is this a reportable quantity?

RQ Threshold:

Is this a marine pollutant?

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)
- ☐ Special Permit; DOT-SP
- ☐ Special Provision (listed in Column 7 of 49 CFR 172.101);
SP#

ADD'L STORAGE INFORMATION

Is the Product...

- Controlled Substance? Controlled Substance Code
- Controlled by State(s)? Listed Chemical (List I or II)
- ARCOS Reportable? If yes, indicate which:
- Schedule No. Is it a scheduled listed chemical product?:

CLASS OF TRADE RESTRICTION:

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:

SDS Hazard Classification

- ☒ Organic
- ☐ Inorganic
- ☐ Steroid/Androgen

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:

NFPA Storage Level:

Is the product a NIOSH hazardous drug?

If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code:

Waste Characteristics

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

If Yes, is it managed with a pharmacy registry?

Website URL:

Med Guide Required

Limited Distribution Requirement

Comments / Details: (For example, iPledge program?)

REMS:

REMS Program Manager Name:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:

Site Enrollment Number assigned by Supplier:

Phone:

DEA #:

NCPDP#:

NPI #:

Comments

Registry:

Registry Program Contact Name:

Phone:

Comments

RETURN INSTRUCTIONS

Contact tel. # if product 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 and/or Image of Product Barcode:

Release DATE



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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 ☐ c. Fax ☐ d. Phone only ☐ e. Supplier Web Site only ☐ Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone: Fax Number: Fax Number: Phone No.: Site Address:	Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Days 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: Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight and Priority Overnight PO Processing Overnight receipt available: ☐ PO Receipt cut off time: Days of week overnight is available: ☐ Monday ☐ Tuesday ☐ Wednesday ☐ Thursday ☐ Friday Priority Overnight receipt available: ☐ PO Receipt Cut off time: Saturday Overnight receipt available: ☐ PO Receipt Cut off time: Order receipt method: Phone: Phone #: Fax: Fax #: EDI: Overnight Fees apply: ☐ Other fees apply: ☐
Class of Trade Restriction: 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:	
Other Data Information Required to Process PO: Patient Procedure Date: Physician Name: Physician/Clinic Phone #: Physician State License #: Physician/Clinic DEA #: Physician/Clinic Specialty:	Return Instructions 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? ☐