



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

Version 2021 Introduction Type:  Post Launch Change  Final Version Date: 6/23/2024

**PRODUCT INFORMATION**

Company Name: Camber Pharmaceuticals, Inc. Application: ANDA  
 Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 040901  
 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: 31722-522-01 Unit of Use NDC: CVX Code: UPC: 331722522014  
 UDI: MVX Code:  
 Description: Hydralazine Hydrochloride Tablets, USP 100 mg  
 Active Ingredient(s): Hydralazine hydrochloride, USP  
 URL for Additional Product Information: [www.camberpharma.com](http://www.camberpharma.com)  
 Address: 800 Centennial Ave, Suite 1 Address 2:  
 City: Piscataway State: NJ Zip: 08854  
 Key Contact: Customer Service Email: [customerservice@camberpharma.com](mailto:customerservice@camberpharma.com)  
 Phone Number: 1-866-827-3647 Fax: 732-562-8788  
 Product Therapeutic Classification: Vasodilator

**SPECIAL HANDLING AND STORAGE REQUIREMENTS\***

a. Temperature – Indicate the USP temperature range for this product.  
 Temperature Range: Controlled Room – between 20 and 25 C (68° – 77° F)  
 Other Temperature Range Requirement (write in):  
 Notes:  
 Is this product to be shipped to customers on ice?  No  
 Is this product to be shipped to customers on dry ice?  No

b. Contact for temperature excursion questions:  
 Name: Soma Raju  
 Number: 732-529-0423  
 Group E-mail: [somaraju@heterousa.com](mailto:somaraju@heterousa.com)

c. Special regulations for product in any states?  
 Special returns requirements for this product?  No

d. Store product (unit of sale) upright?  No  
 Protect product (unit of sale) from light?  No

e. Shelf life:  
 Initial shelf life at launch (if different): 24 Months

| ADDITIONAL PRODUCT INFORMATION                                      |                              | PRODUCT DESCRIPTION INFORMATION                               |   |
|---|------------------------------|---|---|
| The product is a legend device? if yes, enter class #               | <input type="checkbox"/> No  | Is the Product... Direct-Ship Only                            | <input type="checkbox"/>  |
| a product kit?  | <input type="checkbox"/> No  | Is the Product... Neither                                     | <input type="checkbox"/>  |
| if yes, list NDCs of component parts reverse numbered?              |                              | Orphan Drug Status  |   |
| co-licensed?  | <input type="checkbox"/> No  | FDA Approval Status   |   |
| latex-free?   | <input type="checkbox"/> No  | Allergens Present   |   |
| preservative-free?  | <input type="checkbox"/> Yes | Country of Origin   | India   |
| correctional institution block?                                     | <input type="checkbox"/> No  | Is this product covered under the Trade Agreements Act (TAA)? | <input type="checkbox"/> No                                     |
| opioid?   | <input type="checkbox"/> No  |   |   |
| Cannabinoid?  | <input type="checkbox"/> No  |   |   |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? |                              |   |   |
| If Unit Dose, indicate NDC here:                                    |                              |   |   |
|   |                              | Size:   | 100 ct  |
|   |                              | Strength:   | 100 mg  |
|   |                              | Dosage Form:  | Tablet  |
|   |                              | Product Shape:  | Round   |
|   |                              | Product Color:  | Orange  |
|   |                              | Product Imprint:  | Unscored, debossed with 'H' one side and '41' on the other side |

**ORDER INFORMATION**

Unit of Sale:  Bottle,  Box/Carton,  Ampule,  Glass,  Tube,  Vial Liquid Sgl,  Vial Liquid Multi,  Vial Powder Sgl,  Vial Powder Multi,  Other: Write In

What is the NDC selling unit?  
 1 Bottle of 100 Tablets  
 (Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity?  Yes

If Yes, how many of which package type?  
 24 Each, Inner/ Carton/ Pack, Case

**FOR GENERIC DRUG PRODUCTS**

Authorized Generic \*If Authorized Generic, other section fields are not applicable

I. Orange Book Rating: AA  
 II. Generic Equivalent to What Brand?: Hydralazine Hydrochloride Tablets (Pliva)

**PHARMACY ORDER / BILL UNIT**

Rec. sell unit to customer? (Write-in, e.g. 1 Vial)  
 Rx billing unit to pharmacy:  Each,  Gram,  Milliliter

**DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION**

Does supplier meet DSCSA definition of manufacturer?  Yes,  No  
 Is product exempt from DSCSA?  No  
 If yes, select exemption: Other exemption - Write in:  
 Is product repackaged?  No  
 Is product sold by manufacturer's exclusive distributor?  Yes  
 Has FDA granted waiver/exception/exemption for product?  No  
 If yes, attach documentation from FDA.

GLN: 0331722498975  
 GCP:

If yes, was original product purchased direct from mfr?  No  
 Provide source manufacturer for repackaged product:

**ITEM AND PACKING INFORMATION**

| Item/Each:                     | Weight Lbs. | Dimensions (US msmts.) |       |        | Volume (Cube) | Saleable # Pieces |
|--------------------------------|-------------|------------------------|-------|--------|---------------|-------------------|
|                                |             | Depth                  | Width | Height |               |                   |
| Box/Carton/Bundle/ Inner Pack: | 0.16        | 2                      | 2     | 3.5    | 14.00         | 1                 |
| Case:                          | 4.5         | 12.5                   | 8.5   | 4.5    | 478.13        | 24                |
| Pallet:                        |             |                        |       |        |               |                   |

**GTIN AND HIBCC PRODUCT INFORMATION**

| Saleable Unit of Measure   | Saleable Quantity | HIBCC | GTIN-14        | Unit of Use GTIN-14 |
|--|-------------------|-------|----------------|---------------------|
| <input checked="" type="checkbox"/> Item/Each                    | 1                 |       | 00331722522014 |                     |
| <input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack |                   |       |                |                     |
| <input checked="" type="checkbox"/> Case                         | 24                |       | 20331722522018 |                     |
| <input type="checkbox"/> Pallet                                  |                   |       |                |                     |

**COST INFORMATION**

Regular Cost  
 Invoice Cost (WAC) (\$) \$14.21  
 As of date: 4/15/2024

**WHOLESALE USE ONLY:**  
 Vendor #:  
 Whsl. Code #:  
 Finline Code:



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

Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

| MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION  |  |   |                                    |                                    |                                   |   |   |                                |                             |                   |                             |                         |                      |              |                      |   |                             |
|--|--|---|------------------------------------|------------------------------------|-----------------------------------|---|---|--------------------------------|-----------------------------|-------------------|-----------------------------|-------------------------|----------------------|--------------|----------------------|---|-----------------------------|
| <p>Is this product (check all that apply):</p> <p>a. Cytotoxic? <input type="checkbox"/> No</p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant?<br/>           Is the product a CA Prop 65 carcinogen? <input type="checkbox"/> No<br/>           Is the product a CA Prop 65 reproductive toxicant? <input type="checkbox"/> No<br/>           Does the product label bear a CA Prop 65 warning? <input type="checkbox"/> No</p> <p>c. Contact Hazard? <input type="checkbox"/> No</p> <p>d. Does this product require special clean-up instructions?<br/>           (If yes, attach SDS with special instructions.) <input type="checkbox"/> No</p> <p>e. Does the product contain DEHP? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by DOT?<br/>           (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by IATA?<br/>           (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is the product restricted for air shipment? If so, indicate restriction: <input type="checkbox"/> No</p> <p><input type="checkbox"/> Passenger<br/> <input type="checkbox"/> Cargo<br/> <input type="checkbox"/> Passenger &amp; Cargo</p> <p>Is this a reportable quantity? <input type="checkbox"/> No<br/>           RQ Threshold: <input type="text"/></p> <p>Is this a marine pollutant? <input type="checkbox"/> No</p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit?<br/> <input type="checkbox"/> No (if yes, identify method below)</p> <p><input type="checkbox"/> Limited Quantity<br/> <input type="checkbox"/> Consumer Commodity, ORM-D<br/> <input type="checkbox"/> Small Quantity (49 CFR 173.4)<br/> <input type="checkbox"/> Special Permit; DOT-SP<br/> <input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101);<br/>           SP# <input type="text"/></p> | <div style="background-color: #2c4e64; color: white; padding: 2px; text-align: center; font-weight: bold;">SDS Hazard Classification</div> <table style="width:100%; border: none;"> <tr> <td style="width: 50%; border: none;"><input checked="" type="checkbox"/> Organic</td> <td style="width: 50%; border: none;"><input type="checkbox"/> Corrosive</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Inorganic</td> <td style="border: none;"><input type="checkbox"/> Oxidizer</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Steroid/Androgen</td> <td style="border: none;"><input type="checkbox"/> Contact Hazard</td> </tr> </table> <p>Does the product have an Aerosol class? If yes, identify NFPA Storage Level: <input type="text"/> No</p> <p>NFPA Storage Level: <input type="text"/></p> <p>Is the product a NIOSH hazardous drug? <input type="checkbox"/> No<br/>           If yes, indicate which: <input type="text"/></p> | <input checked="" type="checkbox"/> Organic | <input type="checkbox"/> Corrosive | <input type="checkbox"/> Inorganic | <input type="checkbox"/> Oxidizer | <input type="checkbox"/> Steroid/Androgen | <input type="checkbox"/> Contact Hazard |                                |                             |                   |                             |                         |                      |              |                      |   |                             |
| <input checked="" type="checkbox"/> Organic  | <input type="checkbox"/> Corrosive   |   |                                    |                                    |                                   |   |   |                                |                             |                   |                             |                         |                      |              |                      |   |                             |
| <input type="checkbox"/> Inorganic   | <input type="checkbox"/> Oxidizer  |   |                                    |                                    |                                   |   |   |                                |                             |                   |                             |                         |                      |              |                      |   |                             |
| <input type="checkbox"/> Steroid/Androgen  | <input type="checkbox"/> Contact Hazard  |   |                                    |                                    |                                   |   |   |                                |                             |                   |                             |                         |                      |              |                      |   |                             |
| Hazardous Waste Identification   |  |   |                                    |                                    |                                   |   |   |                                |                             |                   |                             |                         |                      |              |                      |   |                             |
| EPA Hazardous Waste Code: <input type="text"/> Waste Characteristics: <input type="text"/>   |  |   |                                    |                                    |                                   |   |   |                                |                             |                   |                             |                         |                      |              |                      |   |                             |
| REMS or REGISTRY RESTRICTIONS  |  |   |                                    |                                    |                                   |   |   |                                |                             |                   |                             |                         |                      |              |                      |   |                             |
| <p>Is there a REMS on this product? <input type="checkbox"/> No</p> <p>If Yes, is it managed with a pharmacy registry? <input type="text"/></p> <p>Website URL: <input type="text"/></p> <p>Med Guide Required <input type="checkbox"/> No</p> <p>Limited Distribution Requirement <input type="text"/></p> <p>Comments / Details: (For example, iPledge program?) <input type="text"/></p> <p><b>REMS:</b> <input type="checkbox"/> No</p> <p>REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input type="text"/></p> <p>Wholesale distributor support: <input type="text"/></p> <p>Provider Name: <input type="text"/> DEA #: <input type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input type="text"/> NCPDP#: <input type="text"/></p> <p>NPI #: <input type="text"/></p> <p>Comments <input type="text"/></p> <p><b>Registry:</b> <input type="checkbox"/> No</p> <p>Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/></p> <p>Comments <input type="text"/></p>   |  |   |                                    |                                    |                                   |   |   |                                |                             |                   |                             |                         |                      |              |                      |   |                             |
| RETURN INSTRUCTIONS  |  |   |                                    |                                    |                                   |   |   |                                |                             |                   |                             |                         |                      |              |                      |   |                             |
| <p>Contact tel. # if product received damaged: <input type="text"/> 1-866-827-3647</p> <p>Is product returnable for credit: <input type="checkbox"/> Yes</p> <p>URL/Link to returns policy: <input type="text"/> contact - customerservice@camberpharma.com</p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> No</p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>  |  |   |                                    |                                    |                                   |   |   |                                |                             |                   |                             |                         |                      |              |                      |   |                             |
| ADD'L STORAGE INFORMATION  |  |   |                                    |                                    |                                   |   |   |                                |                             |                   |                             |                         |                      |              |                      |   |                             |
| <p>Is the Product...</p> <table style="width:100%; border: none;"> <tr> <td style="width: 30%;">Controlled Substance?</td> <td style="width: 10%;"><input type="checkbox"/> No</td> <td style="width: 30%;">Controlled Substance Code</td> <td style="width: 30%;"><input type="text"/></td> </tr> <tr> <td>Controlled by State(s)?</td> <td><input type="checkbox"/> No</td> <td>Listed Chemical (List I or II)</td> <td><input type="checkbox"/> No</td> </tr> <tr> <td>ARCOS Reportable?</td> <td><input type="checkbox"/> No</td> <td>If yes, indicate which:</td> <td><input type="text"/></td> </tr> <tr> <td>Schedule No.</td> <td><input type="text"/></td> <td>Is it a scheduled listed chemical product?:</td> <td><input type="checkbox"/> No</td> </tr> </table>   |  | Controlled Substance?                       | <input type="checkbox"/> No        | Controlled Substance Code          | <input type="text"/>              | Controlled by State(s)?                   | <input type="checkbox"/> No             | Listed Chemical (List I or II) | <input type="checkbox"/> No | ARCOS Reportable? | <input type="checkbox"/> No | If yes, indicate which: | <input type="text"/> | Schedule No. | <input type="text"/> | Is it a scheduled listed chemical product?: | <input type="checkbox"/> No |
| Controlled Substance?  | <input type="checkbox"/> No  | Controlled Substance Code                   | <input type="text"/>               |                                    |                                   |   |   |                                |                             |                   |                             |                         |                      |              |                      |   |                             |
| Controlled by State(s)?  | <input type="checkbox"/> No  | Listed Chemical (List I or II)              | <input type="checkbox"/> No        |                                    |                                   |   |   |                                |                             |                   |                             |                         |                      |              |                      |   |                             |
| ARCOS Reportable?  | <input type="checkbox"/> No  | If yes, indicate which:                     | <input type="text"/>               |                                    |                                   |   |   |                                |                             |                   |                             |                         |                      |              |                      |   |                             |
| Schedule No.   | <input type="text"/>   | Is it a scheduled listed chemical product?: | <input type="checkbox"/> No        |                                    |                                   |   |   |                                |                             |                   |                             |                         |                      |              |                      |   |                             |
| CLASS OF TRADE RESTRICTION:  |  |   |                                    |                                    |                                   |   |   |                                |                             |                   |                             |                         |                      |              |                      |   |                             |
| <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Yes</p> <p>Restricted to retail pharmacy only: <input type="checkbox"/> No</p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> No</p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/> No</p> <p>Comments: <input type="text"/></p>  |  |   |                                    |                                    |                                   |   |   |                                |                             |                   |                             |                         |                      |              |                      |   |                             |
| MISCELLANEOUS NOTES and/or Image of Product Barcode:   |  |   |                                    |                                    |                                   |   |   |                                |                             |                   |                             |                         |                      |              |                      |   |                             |
| Release DATE   |  |   |                                    |                                    |                                   |   |   |                                |                             |                   |                             |                         |                      |              |                      |   |                             |



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