



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

Version 2024 Introduction Type: Final Version Date:

PRODUCT INFORMATION	
Company Name:	Camber Pharmaceuticals, Inc.
Application Number for NDA/ANDA/BLA; PMA/510(k):	216937
Medical Device Class, if applicable:	
DUNS:	11-856-3719
Proprietary Name (If Applicable) and Established Name:	Nimodipine Oral Solution 60 mg/20 mL (3 mg/mL)
Selling Unit NDC:	31722-039-47
Unit of Use NDC:	
UPC:	331722039475
CVX Code:	
MXV Code:	
Description:	Nimodipine Oral Solution 60 mg/20 mL (3 mg/mL)
Active Ingredient(s):	Nimodipine
URL for Additional Product Information:	www.camberpharma.com
Address:	800 Centennial Ave, Suite 1
City:	Piscataway
Key Contact:	Customer Service
Phone Number:	1-866-827-3647
Product Therapeutic Classification:	Dihydropyridine calcium channel blocker

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)	Excursions permitted to 15°C to 30°C (59°F to 86°F).
Notes	Do not refrigerate.
Is this product to be shipped to customers on ice?	<input type="text" value="No"/>
Is this product to be shipped to customers on dry ice?	<input type="text" value="No"/>
b. Contact for temperature excursion questions:	
Name:	Soma Raju
Number:	732-529-0423
Group E-mail:	somaraju@heterousa.com
c. Special regulations for product in any states?	
Special returns requirements for this product?	<input type="text" value="No"/>
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	<input type="text" value="No"/>
e. Shelf life:	
Initial shelf life at launch (if different):	<input type="text" value="24"/> Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is?		Is the Product... Direct-Ship Only	<input type="text" value="Neither"/>
a legend device?	<input type="text" value="No"/>	Is the Product... Orphan Drug Status	
if yes, enter class #		FDA Approval Status	
a product kit?	<input type="text" value="No"/>	Allergens Present	<input type="text" value="Alcohol"/>
if yes, list NDCs of component parts		Country of Origin	<input type="text" value="India"/>
reverse numbered?	<input type="text" value="No"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="No"/>
co-licensed?	<input type="text" value="No"/>		
latex-free?	<input type="text" value="Yes"/>		
preservative-free?	<input type="text" value="No"/>		
correctional institution block?	<input type="text" value="No"/>		
opioid?	<input type="text" value="No"/>		
Cannabinoid?	<input type="text" value="No"/>		
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text" value=""/>		
If Unit Dose, indicate NDC here:	<input type="text" value=""/>		
		Size:	<input type="text" value="473 mL"/>
		Strength:	<input type="text" value="60 mg/20 mL (3 mg/mL)"/>
		Dosage Form:	<input type="text" value="Oral solution"/>
		Product Shape:	<input type="text" value="N/A"/>
		Product Color:	<input type="text" value="Pale yellow"/>
		Product Imprint:	<input type="text" value="N/A"/>

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	<input type="text" value="1 Bottle of 473 mL Oral Solution"/>
<input type="checkbox"/> Box/ Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity? <input type="text" value="Yes"/>
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	<input type="text" value="24"/> Each
<input type="checkbox"/> Vial Powder Multi	<input type="text" value=""/>
<input type="checkbox"/> Other: Write In	<input type="text" value=""/>
	Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text" value="No TE Code. This product is the Reference Standard."/> <input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable
II. Generic Equivalent to What Brand?:	<input type="text" value="n/a"/>

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="text" value=""/>	<input type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
HCPCS J-Code:	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="text" value="Yes"/>
Is product exempt from DSCSA?	<input type="text" value="No"/>
If yes, select exemption:	<input type="text" value=""/>
Other exemption - Write in:	
Is product repackaged?	<input type="text" value="No"/>
Is product sold by manufacturer's exclusive distributor?	<input type="text" value="Yes"/>
Has FDA granted waiver/exception/exemption for product?	<input type="text" value="No"/>
If yes, attach documentation from FDA.	
GLN:	<input type="text" value="0331722498975"/>
GCP:	<input type="text" value=""/>
If yes, was original product purchased direct from mfr?	<input type="text" value=""/>
Provide source manufacturer for repackaged product	<input type="text" value=""/>

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Box/ Carton/ Bundle/ Inner Pack:	1.33	2.69	2.69	7.5	54.27	1
Case:	33.9	16.5	11.5	9	1707.75	24
Pallet:						

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14
<input checked="" type="checkbox"/> Item/Each	N	1		00331722039475
<input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack				
<input checked="" type="checkbox"/> Case	N	24		20331722039479
<input type="checkbox"/> Pallet				

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost	<input type="text" value=""/>	Vendor #:	<input type="text" value=""/>
Invoice Cost (WAC) (\$)	\$2,132.73	Whst. Code #:	<input type="text" value=""/>
As of date:	1/3/2025	Fineline Code:	<input type="text" value=""/>

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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? No

b. CA Prop. 65 Carcinogen or Reproductive Toxicant?
Is the product a CA Prop 65 carcinogen? Yes
Is the product a CA Prop 65 reproductive toxicant? Yes
Does the product label bear a CA Prop 65 warning? No

c. Contact Hazard? No

d. Does this product require special clean-up instructions?
(If yes, attach SDS with special instructions.) No

e. Does the product contain DEHP? No

Is this product regulated for shipment by DOT?
(if yes, answer a-e below and provide SDS) No

a. UN/Identification Number

b. Proper Shipping Name

c. DOT Hazard Class

d. Packing Group Calcium channel blo

e. Inhalation Hazard?

Is this product regulated for shipment by IATA?
(if yes, answer a-e below and provide SDS) No

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: No

Passenger
 Cargo
 Passenger & Cargo

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

SDS Hazard Classification	
<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
Does the product have an Aerosol class? If yes, identify NFPA Storage Level: <input type="text"/>	<input type="checkbox"/> No
NFPA Storage Level: <input type="text"/>	
Is the product a NIOSH hazardous drug? If yes, indicate which: <input type="text"/>	<input type="checkbox"/> No

Hazardous Waste Identification	
EPA Hazardous Waste Code: <input type="text"/>	Waste Characteristics <input type="text"/>

REMS or REGISTRY RESTRICTIONS	
Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL: <input type="text"/>	<input type="checkbox"/> No
Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?) <input type="text"/>	<input type="checkbox"/> No
REMS: REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/> Supplier Manages REMS registry exclusively: <input type="text"/> Wholesale distributor support: <input type="text"/> Provider Name: <input type="text"/> DEA #: <input type="text"/> Site Enrollment Number assigned by Supplier: <input type="text"/> NCPDP#: <input type="text"/> NPI #: <input type="text"/> Comments <input type="text"/>	
Registry: Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/> Comments <input type="text"/>	<input type="checkbox"/> No

ADD'L STORAGE INFORMATION	
Is the Product... Controlled Substance? <input type="checkbox"/> No Controlled by State(s)? <input type="checkbox"/> No ARCOS Reportable? <input type="checkbox"/> No Schedule No. <input type="text"/>	Controlled Substance Code <input type="text"/> Listed Chemical (List I or II) <input type="checkbox"/> No If yes, indicate which: <input type="text"/> Is it a scheduled listed chemical product?: <input type="checkbox"/> No

CLASS OF TRADE RESTRICTION:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Yes	
Restricted to retail pharmacy only: <input type="checkbox"/> No	
Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> No	
Restricted from US territories? (explain in comments) <input type="checkbox"/> No	
Comments: <input type="text"/>	

RETURN INSTRUCTIONS	
Contact tel. # if product received damaged: <input type="text"/>	1-866-827-3647
Is product returnable for credit: <input type="checkbox"/> Yes	
URL/Link to returns policy: <input type="text"/>	contact - customerservice@camberpharma.com
Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> No	
If so, which states? Other requirements? Comments? <input type="text"/>	

MISCELLANEOUS 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 <input type="checkbox"/> b. Autofax <input type="checkbox"/> c. Fax <input type="checkbox"/> d. Phone only <input type="checkbox"/> e. Supplier Web Site only <input type="checkbox"/> Minimum Order Quantity: <input type="text"/> Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: <input type="text"/> Name: <input type="text"/> Phone: <input type="text"/>	Purchase order daily receipt cut off time by supplier Cut off time: <input type="text"/> Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days Ships same day for next day receipt: <input type="checkbox"/> Ships for second day receipt: <input type="checkbox"/> 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"/> Drop Ship service fee billed with each order: <input type="text"/> Drop Ship miscellaneous fees billed: <input type="text"/> Comments: <input type="text"/>	Overnight receipt available: <input type="checkbox"/> PO Receipt cut off time: <input type="text"/> Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday Priority Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Saturday Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Order receipt method: <input type="text"/> Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/> Overnight Fees apply: <input type="checkbox"/> 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"/> Restricted to retail pharmacy only: <input type="checkbox"/> Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> Restricted from US territories? (explain in comments) <input type="checkbox"/> Comments: <input type="text"/>	
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: <input type="text"/> Physician Name: <input type="text"/> Physician/Clinic Phone #: <input type="text"/> Physician State License #: <input type="text"/> Physician/Clinic DEA #: <input type="text"/> Physician/Clinic Specialty: <input type="text"/>	Contact # if product is received damaged: <input type="text"/> Is product returnable for credit: <input type="checkbox"/> URL/Link to returns policy: <input type="text"/> Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> If so, which states? Other requirements? Comments? <input type="text"/>
Miscellaneous Notes:	
<input type="text"/>	
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>