



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

Version 2024 Introduction Type:  New Item  Final Version Date: 9/8/2025

**PRODUCT INFORMATION**

Company Name: MILLA PHARMACEUTICALS INC Application: ANDA  
 Application Number for NDA/ANDA/BLA; PMA/510(k): A211081  
 Medical Device Class, if applicable:  
 DUNS: 119319487  
 Proprietary Name (If Applicable) and Established Name:  
 Selling Unit NDC: 81284-0213-01 Unit of Use NDC: 81284-0213-00 UPC: 381284213011  
 UDI CVX Code: MVX Code:  
 Description: Phenylephrine 10mg/mL 10 mL x 1 vial  
 Active Ingredient(s): Phenylephrine  
 URL for Additional Product Information:  
 Address: 1310 Highway 96E Address 2: Suite 104A  
 City: White Bear Lake State: MN Zip: # 55110  
 Key Contact: Siddharth Nirmal Email: [siddharth.nirmal@aforalpharma.com](mailto:siddharth.nirmal@aforalpharma.com)  
 Phone Number: +1 302 946 0117 Fax:  
 Product Therapeutic Classification:

**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: DL-QA GPI Pharma  
 Number:  
 Group E-mail: [qa@gpipharma.ie](mailto:qa@gpipharma.ie)

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?  Yes

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

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is? a legend device? <input type="checkbox"/> No	Is the Product... Is the Product... <input type="checkbox"/> Direct-Ship Only <input type="checkbox"/> Unit of Use	Size:	10mL
if yes, enter class # a product kit? <input type="checkbox"/> No	Orphan Drug Status	Strength:	10mg/mL
if yes, list NDCs of component parts reverse numbered? <input type="checkbox"/> No	FDA Approval Status	Dosage Form:	Injectable
co-licensed? <input type="checkbox"/> No	Allergens Present	Product Shape:	NA
latex-free? <input type="checkbox"/> Yes	Country of Origin	Product Color:	NA
preservative-free? <input type="checkbox"/> Yes	India	Product Imprint:	NA
correctional institution block? opioid? <input type="checkbox"/> No	Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No		
Cannabinoid? <input type="checkbox"/> No			
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/> Yes			
If Unit Dose, indicate NDC here:			

**ORDER INFORMATION**

Unit of Sale	What is the NDC selling unit?
<input type="checkbox"/> Bottle	1 vial
<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="checkbox"/> Yes
<input type="checkbox"/> Tube	
<input checked="" 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	8 Each
<input type="checkbox"/> Vial Powder Multi	Inner/ Carton/Pack
<input type="checkbox"/> Other: Write In	Case

**FOR GENERIC DRUG PRODUCTS**

I. Orange Book Rating: AP  Authorized Generic \*If Authorized Generic, other section fields are not applicable  
 II. Generic Equivalent to What Brand?: Biorphen

**PHARMACY ORDER / BILL UNIT**

Rec. sell unit to customer? 1 vial  
 (Write-in, e.g. 1 Vial)  
 HCPCS J-Code:  
 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?  
 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: 0381284000000  
 GCP:  
 If yes, was original product purchased direct from mfr?  
 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:	0.052316	0.972	0.972	2.183	2.0624635	1
Case:	0.072642	1.575	1.181	2.52	4.687389	1
Pallet:	10.33966	13.976	9.567	6.496	868.56971	112
	806.18544	48	40	44.882	86173.44	8064

**GTIN AND HIBCC PRODUCT INFORMATION**

Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each		1			381284213004
<input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack		112		00381284213011	
<input checked="" type="checkbox"/> Case		8064		20381284213015	
<input checked="" type="checkbox"/> Pallet					

**COST INFORMATION**

Regular Cost  
 Invoice Cost (WAC) (\$) \$18.00  
 As of date: 6/24/2022

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

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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?  
 (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

Corrosive  
 Oxidizer  
 Contact Hazard

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:  Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:  DEA #:

Site Enrollment Number assigned by Supplier:  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:



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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"/>	<b>Purchase order daily receipt cut off time by supplier</b> 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"/>	<b>Overnight receipt available:</b> <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 <b>Priority Overnight receipt available:</b> <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> <b>Saturday Overnight receipt available:</b> <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"/>