



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

Version 2020 Introduction Type:  Post Launch Change  Final Version Date:

PRODUCT INFORMATION	
Company Name:	<input type="text" value="Xiromed LLC"/>
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	<input type="text" value="212968"/>
DUNS:	<input type="text" value="080228637"/>
Proprietary Name (If Applicable) and Established Name:	<input type="text" value="NEOSTIGMINE METHYLSULFATE"/>
Selling Unit NDC:	<input type="text" value="70700-171-23"/>
UDI	<input type="text"/>
Description:	<input type="text" value="Neostigmine Methylsulfate Injection, USP 5 mg/10 mL"/>
Active Ingredient(s):	<input type="text" value="NEOSTIGMINE METHYLSULFATE"/>
URL for Additional Product Information:	<input type="text"/>
Address:	<input type="text" value="180 Park Ave"/>
City:	<input type="text" value="Florham Park"/>
Key Contact:	<input type="text" value="David Hernandez"/>
Phone Number:	<input type="text" value="844-947-6633"/>
Product Therapeutic Classification:	<input type="text"/>
Application:	<input type="text" value="ANDA"/>
Unit of Use NDC:	<input type="text" value="370700171233"/>
UPC:	<input type="text"/>
CVX Code:	<input type="text"/>
MX Code:	<input type="text"/>
Address 2:	<input type="text" value="Suite 101"/>
State:	<input type="text" value="NJ"/>
Zip:	<input type="text" value="07932"/>
Email:	<input type="text" value="david.hernandez@xiromed.com"/>
Fax:	<input type="text" value="862-286-0932"/>

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
Temperature Range	<input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>
Other Temperature Range Requirement (write in)	<input type="text"/>
Notes	<input type="text"/>
Is this product to be shipped to customers on dry ice?	<input type="text" value="No"/>
Is this product to be shipped to customers on dry ice?	<input type="text" value="No"/>
<b>b. Contact for temperature excursion questions:</b>	
Name:	<input type="text" value="Vipul Gandhi"/>
Number:	<input type="text" value="862-895-6230"/>
Group E-mail:	<input type="text" value="vipul.gandhi@xiromed.com"/>
<b>c. Special regulations for product in any states?</b>	
Special returns requirements for this product?	<input type="text" value="No"/>
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	<input type="text" value="Yes"/>
<b>e. Shelf life:</b>	
Initial shelf life at launch (if different):	<input type="text" value="24"/> Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device?	<input type="text" value="No"/>	Is the Product... Direct-Ship Only	<input type="text"/>
If yes, enter class # a product kit?	<input type="text"/>	Is the Product... Orphan Drug Status	<input type="text" value="Neither"/>
If yes, list NDCs of component parts reverse numbered?	<input type="text"/>	FDA Approval Status	<input type="text"/>
co-licensed?	<input type="text" value="No"/>	Allergens Present	<input type="text"/>
latex-free?	<input type="text" value="Yes"/>	Country of Origin	<input type="text" value="India"/>
preservative-free?	<input type="text" value="No"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="No"/>
correctional institution block?	<input type="text" value="Yes"/>		
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"/>		
If Unit Dose, indicate NDC here:	<input type="text"/>		
Size:	<input type="text" value="10 x 10 mL Multiple Dose Vials"/>	Strength:	<input type="text" value="5MG/10ML (0.5MG/ML)"/>
Dosage Form:	<input type="text" value="SOLUTION"/>	Product Shape:	<input type="text"/>
Product Color:	<input type="text"/>	Product Imprint:	<input type="text"/>

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

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text" value="AP"/>
II. Generic Equivalent to What Brand?:	<input type="text" value="BLOXIVERZ®"/>
	<input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	<input type="text" value="1 Box of 10 Vials"/>
	(Write-in, e.g. 1 Vial)
Rx billing unit to pharmacy:	<input checked="" type="checkbox"/> Each
	<input type="checkbox"/> Gram
	<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"/>
Other exemption - Write in:	<input type="text"/>
Is product repackaged?	<input type="text" value="No"/>
Is product sold by manufacturer's exclusive distributor?	<input type="text" value="No"/>
Has FDA granted waiver/exception/exemption for product?	<input type="text" value="No"/>
GLN:	<input type="text" value="0370700000007"/>
If Yes, was original product purchased direct from mfr?	<input type="text"/>
If yes, attach documentation from FDA.	<input type="text"/>

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Width	Height		
Box/Carton/Bundle/Inner Pack:	0.73	7.28	2.87	2.56	53.487616	1
Case:	12.789	15.157	11.811	5.512	986.75453	16
Pallet:					0	

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
Item/Each	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	<input type="text" value="1"/>	<input type="text"/>	<input type="text" value="10370700171230"/>	<input type="text"/>
<input checked="" type="checkbox"/> Case	<input type="text" value="16"/>	<input type="text"/>	<input type="text" value="20370700171237"/>	<input type="text"/>
<input checked="" type="checkbox"/> Pallet	<input type="text" value="1,008"/>	<input type="text"/>	<input type="text" value="30370700171234"/>	<input type="text"/>

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost	<input type="text"/>	Vendor #:	<input type="text"/>
Invoice Cost (WAC) (\$)	<input type="text" value="\$170.00"/>	Whsl. Code #:	<input type="text"/>
As of date:	<input type="text"/>	Fineline Code:	<input type="text"/>

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



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Version 2020

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?  No  
 Is the product a CA Prop 65 reproductive toxicant?  No  
 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

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:

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#

### ADD'L STORAGE INFORMATION

Is the Product...

Controlled Substance?  No Controlled Substance Code

Controlled by State(s)?  No Listed Chemical (List I or II)  No

ARCOS Reportable?  No If yes, indicate which:

Schedule No.  Is it a scheduled listed chemical product?:  No

### CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes

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  Corrosive  
 Inorganic  Oxidizer  
 Steroid/Androgen  Contact Hazard

Aerosol Class; Identify NFPA Storage Level:

Is the product a NIOSH hazardous drug?  No  
 If yes, indicate which:

### Hazardous Waste Identification

EPA Hazardous Waste Code:  Waste Characteristics

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?  No  
 If Yes, is it managed with a pharmacy registry?   
 Website URL:

Med Guide Required  No

Limited Distribution Requirement  No

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:  PCPDP#:   
 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			
Purchase orders may be accepted by:			
a. EDI	<input type="checkbox"/>		
b. Autofax	<input type="checkbox"/>	Fax Number:	<input type="text"/>
c. Fax	<input type="checkbox"/>	Fax Number:	<input type="text"/>
d. Phone only	<input type="checkbox"/>	Phone No.:	<input type="text"/>
e. Supplier Web Site only	<input type="checkbox"/>	Site Address:	<input type="text"/>
Minimum Order Quantity:	<input type="text"/>		
Supplier's Customer Service Number:	<input type="text"/>		
Contracted 3PL company / contact #:	Name:	<input type="text"/>	
	Phone:	<input type="text"/>	

Standard Order Receipt and Processing			
<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:	
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 and Priority Overnight PO Processing	
<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:	Phone: <input type="text"/> Phone #: Fax: <input type="text"/> Fax #: 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:	
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"/>

Return Instructions	
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"/>