



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

Version 2020

Introduction Type:  Open Stock

Final Version

Date: 7/10/2024

PRODUCT INFORMATION	
Company Name:	Xiromed LLC
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	203203
DUNS:	080228637
Proprietary Name (if Applicable) and Established Name:	Lansoprazole
Selling Unit NDC:	70700-263-90
Unit of Use NDC:	
UDI	
UPC:	370700263907
CVX Code:	
MXV Code:	
Description:	Lansoprazole DR Capsules USP, 30mg - 90ct Bottle
Active Ingredient(s):	Lansoprazole
URL for Additional Product Information:	<a href="http://www.xiromed.com">www.xiromed.com</a>
Address:	180 Park Ave
City:	Florham Park
Key Contact:	Xiromed Regulatory
Phone Number:	844-947-6633
Product Therapeutic Classification:	

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
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>b. Contact for temperature excursion questions:</b>	
Name:	Xiromed Quality
Number:	844-947-6633
Group E-mail:	<a href="mailto:US-Quality-Xiromed@xiromed.com">US-Quality-Xiromed@xiromed.com</a>
<b>c. Special regulations for product in any states?</b>	
Special returns requirements for this product?	No
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	No
<b>e. Shelf life:</b>	
Initial shelf life at launch (if different):	24 Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device?	No	Is the Product... Direct-Ship Only	
If yes, enter class # a product kit?	No	Is the Product... Neither	
If yes, list NDCs of component parts reverse numbered?	No	Orphan Drug Status	
co-licensed?	No	FDA Approval Status	
latex-free?	No	Allergens Present	Not made with natural rubber latex.
preservative-free?	Yes	Country of Origin	Spain
correctional institution block?	Yes	Is this product covered under the Trade Agreements Act (TAA)?	Yes
opioid?	No		
Cannabinoid?	No		
If Unit Dose, is item bar coded to unit dose for hospital scanning?			
If Unit Dose, indicate NDC here:			
Size:	90 Count Bottle	Strength:	30mg
Dosage Form:	CAPSULE	Product Shape:	Oval
Product Color:	Opaque white body, light blue cap	Product Imprint:	30mg, A263

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 Bottle of 90 Capsules
<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? Yes
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	If Yes, how many of which package type?
<input type="checkbox"/> Vial Liquid Multi	24 Each
<input type="checkbox"/> Vial Powder Sgl	Inner/ Carton/Pack
<input type="checkbox"/> Vial Power Multi	Case
<input type="checkbox"/> Other: Write In	

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

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
1 Bottle of 90 Capsules	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	No
If yes, select exemption:	GLN: 0370700000007
Other exemption - Write in:	
Is product repackaged?	No
Is product sold by manufacturer's exclusive distributor?	No
Has FDA granted waiver/exception/exemption for product?	No

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Width	Height		
Box/Carton/Bundle/Inner Pack:					0	
Case:	4.3	11.375	7.9375	4.25	383.72852	24
Pallet:					0	

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00370700263907	
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	24		20370700263901	
<input type="checkbox"/> Case				
<input type="checkbox"/> Pallet				

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$27.00	Whsl. Code #:	
As of date:	8/2/2021	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?  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?  No

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?  No

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"/>
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 #:	Name: <input type="text"/>
	Phone: <input type="text"/>
	Fax Number: <input type="text"/>
	Fax Number: <input type="text"/>
	Phone No.: <input type="text"/>
	Site Address: <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="checkbox"/>
Drop Ship service fee billed with each order:	<input type="checkbox"/>
Drop Ship miscellaneous fees billed:	<input type="checkbox"/>
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 #: <input type="text"/>
	Fax: <input type="text"/> Fax #: <input type="text"/>
	EDI: <input type="checkbox"/>
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"/>