



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

Version 2020

Introduction Type: New Item

Final Version

Date: 7/10/2024

PRODUCT INFORMATION	
Company Name:	Xiromed LLC
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	210835
DUNS:	080228637
Proprietary Name (if Applicable) and Established Name:	Testosterone Gel 1.62%
Selling Unit NDC:	70700-112-21
Unit of Use NDC:	
UDI	
UPC:	370700112212
CVX Code:	
MXV Code:	
Description:	Testosterone Transdermal Gel 1.62% - Metered Dose Pump
Active Ingredient(s):	Testosterone
URL for Additional Product Information:	
Address:	180 Park Ave
City:	Florham Park
Key Contact:	Xiromed Regulatory
Phone Number:	844-947-6633
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:	Xiromed Quality
Number:	844-947-6633
Group E-mail:	US-Quality-Xiromed@xiromed.com
c. Special regulations for product in any states?	No
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	Yes
Protect product (unit of sale) from light?	Yes
e. Shelf life:	24 Months
Initial shelf life at launch (if different):	Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device?	No	Is the Product... Direct-Ship Only	
if yes, enter class #		Is the Product... Neither	
if yes, list NDCs of component parts		Orphan Drug Status	
reverse numbered?	No	FDA Approval Status	
co-licensed?	No	Allergens Present	Not made with natural rubber latex.
latex-free?	No	Country of Origin	Spain
preservative-free?	Yes	Is this product covered under the Trade Agreements Act (TAA)?	Yes
correctional institution block?	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:	88g net content - 60 metered pump actuations	Strength:	1.62%
Dosage Form:	Gel	Product Shape:	n/a
Product Color:	Clear Colorless Gel	Product Imprint:	n/a

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 Carton containing 1 Pump Canister
<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	28 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?:	Androgel 1.62%
<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 Canister	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	Gram
	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:	0.4	2.6	2.6	7.4	50.024	1
Case:	11.35	12.1	19.6	9.4	2229.304	28
Pallet:					0	

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
Item/Each	1		00370700112212	00370700112212
Box/ Carton/ Bundle/ Inner Pack				
<input checked="" type="checkbox"/> Case	28		10370700112219	
<input type="checkbox"/> Pallet				

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$88.50	Whsl. Code #:	
As of date:		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:

Signature line



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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? No
 - 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? Yes
- d. Does this product require special clean-up instructions? Yes

(If yes, attach SDS with special instructions.)
- e. Does the product contain DEHP? No

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? No

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? 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? Yes No Controlled Substance Code
- Controlled by State(s)? No Yes Listed Chemical (List I or II) No Yes
- ARCOS Reportable? No Yes If yes, indicate which:
- Schedule No. Is it a scheduled listed chemical product?: No Yes

CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes No
- 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
- Aerosol Class; Identify NFPA Storage Level:
- Is the product a NIOSH hazardous drug? Yes 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 Yes
- If Yes, is it managed with a pharmacy registry? Yes No
- Website URL:
- Med Guide Required Yes No
- Limited Distribution Requirement Yes No
- Comments / Details: (For example, iPledge program?)
- REMS:**
 - REMS Program Manager Name:
 - Supplier Manages REMS registry exclusively: Yes No
 - Wholesale distributor support: Yes No
 - Provider Name:
 - Site Enrollment Number assigned by Supplier:
 - DEA #:
 - PCPDP#:
 - NPI #:
- Comments
- Registry:**
 - Registry Program Contact Name:
 - Phone:
 - Comments

RETURN INSTRUCTIONS

- Contact tel. # if product received damaged:
- Is product returnable for credit: Yes No
- 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:

