



# 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:	<input type="text" value="Xiromed LLC"/>
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	<input type="text" value="210034"/>
DUNS:	<input type="text" value="080228637"/>
Proprietary Name (if Applicable) and Established Name:	<input type="text" value="Clobetasol Propionate"/>
Selling Unit NDC:	<input type="text" value="70700-109-16"/>
UDI	<input type="text" value=""/>
Unit of Use NDC:	<input type="text" value=""/>
UPC:	<input type="text" value="370700109168"/>
CVX Code:	<input type="text" value=""/>
MXV Code:	<input type="text" value=""/>
Description:	<input type="text" value="Clobetasol Propionate Cream USP, 0.05% 30gm Tube"/>
Active Ingredient(s):	<input type="text" value="Clobetasol Propionate"/>
URL for Additional Product Information:	<input type="text" value=""/>
Address:	<input type="text" value="180 Park Ave"/>
City:	<input type="text" value="Florham Park"/>
Key Contact:	<input type="text" value="Xiromed Regulatory"/>
Phone Number:	<input type="text" value="844-947-6633"/>
Product Therapeutic Classification:	<input type="text" value=""/>

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	Controlled Room – between 20 and 25 C (68° – 77° F)
Other Temperature Range Requirement (write in)	<input type="text" value=""/>
Notes	<input type="text" value=""/>
Is this product to be shipped to customers on ice?	<input type="checkbox"/> No
Is this product to be shipped to customers on dry ice?	<input type="checkbox"/> No
b. Contact for temperature excursion questions:	
Name:	<input type="text" value="Xiromed Quality"/>
Number:	<input type="text" value="844-947-6633"/>
Group E-mail:	<input type="text" value="US-Quality-Xiromed@xiromed.com"/>
c. Special regulations for product in any states?	<input type="checkbox"/> No
Special returns requirements for this product?	<input type="checkbox"/> No
d. Store product (unit of sale) upright?	<input type="checkbox"/>
Protect product (unit of sale) from light?	<input type="checkbox"/>
e. Shelf life:	<input type="text" value="24"/> Months
Initial shelf life at launch (if different):	<input type="text" value=""/>

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device?	<input type="checkbox"/> No	Is the Product... Direct-Ship Only	<input type="checkbox"/>
if yes, enter class # a product kit?	<input type="text" value=""/>	Is the Product... Neither	<input type="checkbox"/>
if yes, list NDCs of component parts reverse numbered?	<input type="text" value=""/>	Orphan Drug Status	<input type="checkbox"/>
co-licensed?	<input type="checkbox"/> No	FDA Approval Status	<input type="text" value=""/>
latex-free?	<input type="checkbox"/> No	Allergens Present	<input type="text" value="Not made with natural rubber latex."/>
preservative-free?	<input type="checkbox"/> Yes	Country of Origin	<input type="text" value="Spain"/>
correctional institution block?	<input type="checkbox"/> Yes	Is this product covered under the Trade Agreements Act (TAA)?	<input type="checkbox"/> Yes
opioid?	<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"/>		
If Unit Dose, indicate NDC here:	<input type="text" value=""/>		
		Size:	<input type="text" value="30gm"/>
		Strength:	<input type="text" value="0.05%"/>
		Dosage Form:	<input type="text" value="Topical"/>
		Product Shape:	<input type="text" value=""/>
		Product Color:	<input type="text" value=""/>
		Product Imprint:	<input type="text" value=""/>

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	<input type="text" value="1 Box containing 1 Tube"/>
<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 type="checkbox"/> Vial Liquid Sgl	If Yes, how many of which package type?
<input type="checkbox"/> Vial Liquid Multi	<input type="text" value="48"/> Each
<input type="checkbox"/> Vial Powder Sgl	<input type="text" value=""/>
<input type="checkbox"/> Vial Power Multi	<input type="text" value=""/>
<input type="checkbox"/> Other: Write In	<input type="text" value=""/>

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text" value="AB1"/>
II. Generic Equivalent to What Brand?:	<input type="text" value="Temovate"/>
<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:
<input type="text" value="1 Tube"/>	<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?	<input type="checkbox"/> Yes
Is product exempt from DSCSA?	<input type="checkbox"/> No
If yes, select exemption:	GLN: <input type="text" value="0370700000007"/>
Other exemption - Write in:	<input type="text" value=""/>
Is product repackaged?	<input type="checkbox"/> No
Is product sold by manufacturer's exclusive distributor?	<input type="checkbox"/> No
Has FDA granted waiver/exception/exemption for product?	<input type="checkbox"/> No

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Width	Height		
Item/Each:	0.13	1.85	1.299	7.126	17.124847	1
Box/ Carton/ Bundle/ Inner Pack:					0	
Case:	5.6	12.598	7.165	6.378	575.70807	48
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		00370700109168	
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack				
<input checked="" type="checkbox"/> Case	48		10370700109165	
<input type="checkbox"/> Pallet				

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost	<input type="text" value=""/>	Vendor #:	<input type="text" value=""/>
Invoice Cost (WAC) (\$)	<input type="text" value="\$24.91"/>	Whsl. Code #:	<input type="text" value=""/>
As of date:	<input type="text" value=""/>	Fineline Code:	<input type="text" value=""/>

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:



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

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

SDS Hazard Classification	
<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer
<input checked="" type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard
<input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input type="text"/>	
Is the product a NIOSH hazardous drug? <input type="checkbox"/> No	
If yes, indicate which: <input type="text"/>	

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

### ADD'L STORAGE INFORMATION

Is the Product...		
Controlled Substance?	<input type="checkbox"/> No	Controlled Substance Code <input type="text"/>
Controlled by State(s)?	<input type="checkbox"/> No	Listed Chemical (List I or II) <input type="checkbox"/> No
ARCOS Reportable?	<input type="checkbox"/> No	If yes, indicate which: <input type="text"/>
Schedule No.	<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"/>
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"/>

### RETURN INSTRUCTIONS

Contact tel. # if product 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 and/or Image of Product Barcode:

<input type="text"/>
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