



# 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="70700-109-18"/>
Unit of Use NDC:	<input type="text" value=""/>
UDI:	<input type="text" value=""/>
UPC:	<input type="text" value="370700109182"/>
CVX Code:	<input type="text" value=""/>
MXV Code:	<input type="text" value=""/>
Description:	<input type="text" value="Clobetasol Propionate Cream USP, 0.05% 45gm 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="45gm"/>	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	<input checked="" type="checkbox"/> Bottle
Box/Carton	<input type="checkbox"/>
Ampule	<input type="checkbox"/>
Glass 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	<input type="text" value=""/>
What is the NDC selling unit?	<input type="text" value="1 Box containing 1 Tube"/>
(Write-in, e.g. 1 Box of 10 Vials)	
Minimum order quantity?	<input type="checkbox"/> Yes
If Yes, how many of which package type?	
<input type="text" value="48"/>	Each
<input type="text" value=""/>	Inner/ Carton/Pack
<input type="text" value=""/>	Case

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?	<input type="text" value="1 Tube"/>
Rx billing unit to pharmacy:	<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:	<input type="text" value=""/>
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
GLN:	<input type="text" value="0370700000007"/>
If Yes, was original product purchased direct from mfr?	<input type="checkbox"/>
If yes, attach documentation from FDA.	<input type="text" value=""/>

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Width	Height		
Box/Carton/Bundle/Inner Pack:	0.13	1.85	1.299	7.126	17.124847	1
Case:	6.6	15.748	8.268	6.378	830.44407	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	<input type="text" value="1"/>	<input type="text" value=""/>	<input type="text" value="00370700109182"/>	<input type="text" value=""/>
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	<input type="text" value="48"/>	<input type="text" value=""/>	<input type="text" value="10370700109189"/>	<input type="text" value=""/>
<input type="checkbox"/> Case	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>
<input type="checkbox"/> Pallet	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost	<input type="text" value=""/>	Vendor #:	<input type="text" value=""/>
Invoice Cost (WAC) (\$)	<input type="text" value="\$37.37"/>	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#

### 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
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- 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:

