

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

Version 2020				Introduction Type:	Open Stock	] [	Final Version			Date:	7/10/	/2024	
		PRODUCT INFORMATION					SPECIAL HAN	IDLING AND STO	RAGE REQUI	REMENTS*			
Company Name:	Xiromed LLC Application: ANDA					a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/AN	IDA/BLA (drug); PMA/510(k)(me	ed device): 210	034	•		Tem	perature Range	Controlled Room	– between 20	and 25 C (68	s° – 77° F)		
DUNS:	080228637					Othe	r Temperature Range I	Requirement					
Proprietary Name (If Applicable) a		Clobetasol Propionate				[]	(write in)						
Selling Unit NDC:	70700-109-16	Unit of Use NDC:			0109168	Note	s						
UDI		CVX Code:		MVX Code:		!							
Description:	Description: Clobetasol Propionate Cream USP, 0.05% 30gm Tube Is this product to be shipped to customers on ice? No										-		
Active Ingredient(s):	Is this product to be shipped to customers on dry ice? No Active Ingredient(s):  Clobetasol Propionate									-			
	b. Co								b. Contact for temperature excursion questions:  Name: Xiromed Quality				
URL for Additional Product Inform Address:	180 Park Ave			Address 2: Suite	101	Nam Num			844-947-663				
City:	Florham Park		State:	NJ Zip:		4 1	ip E-mail:				xiromed.co	om	
Key Contact:	Xiromed Regulatory		Email:	usregulatory@xiron		1	- F		oo quanti	7th Officaç	Allonicalor	0111	
Phone Number:	844-947-6633		Fax:	862-286-0932	<u> </u>	c. Special regulation	ns for product in any	states?			No		
Product Therapeutic Classification	n:					Spec	cial returns requirement	ts for this product?			No	_	
	ADDITIONAL DESCRIP	ACT INFORMATION											
	ADDITIONAL PRODU			PRODUCT DESCI	RIPTION INFORMATION	1	nit of sale) upright?						
The product is?		Is the Product Direct-Ship Or	nly				ect product (unit of sa	ale) from light?					
a legend device? if yes, enter class #	No	Is the Product Neither		Size:	30gm	e. Shelf life:	ul abalf life et laureb (	if different).			24	Months	
a product kit?	No	Orphan Drug Status			0.05%	Initia	al shelf life at launch (	it airrerent):				Months	
if yes, list NDCs of	110	FDA Approval Status		Strength:	0.0070			ORDER INFORI	MATION				
component parts				Dosage Form:	Topical								
reverse numbered?	No			Dosage r onn.		Unit	of Sale			NDC selling	unit?		
co-licensed?	No	Allergens Present					Bottle		1 Box contai		01611		
latex-free? preservative-free?	No Yes	Not made with natural rubber late	x.	Product Shape:		)	Box/Carton Ampule		(Write-in, e.	g. 1 Box of 1	U Viais)		
correctional institution block?	Yes					<del>                                   </del>	Glass		Minimum o	rder quantity	<i>i</i> ?	Yes	
opioid?	No			Product Color:			Tube						
Cannabinoid?	No	Country of Origin Spain		Product Imprint:			Vial Liquid Sgl						
If Unit Dose, is item bar coded to u	unit dose for hospital						Vial Liquid Multi				ich package t	type?	
scanning? If Unit Dose, indicate NDC here:		Is this product covered under the Trade Agreements Act (TAA)?	Voc				Vial Powder Sql Vial Power Multi		48	Each Inner/Cartor	/Pook		
II Offic Dose, indicate NDC fiere.		Trade Agreements Not (1741):	Yes				Other: Write In			Case	i/i dok		
		FOR GENERIC DRUG PRODUCTS		<u>.                                    </u>									
									-				
			Autho		norized Generic, other section		PH	IARMACY ORDER	/ BILL UNIT				
I. Orange Book Rating:	AB1			fields a	are not applicable	Rec. sell unit to cu		_	Rx billing u		acy:		
II. Generic Equivalent to What Bra	and?: Temovate						Tube		X	Each			
	DRUGS	SUPPLY CHAIN SECURITY ACT (DSCSA) INFOR	MATION			(Write-in, e.g. 1 Via	1)			Gram Milliliter			
	Dico c	SOLITET STIMIN SESSIVITI ACT (BOSCA) IN SIX	MATION							Willing			
Does supplier meet DSCSA defini	ition of manufacturer?	Yes GLI	ł:	0370700000007			ITEN	I AND PACKING I	NFORMATIO	N			
Is product exempt from DSCSA?		No				]							
If yes, select exemption:							Weight Lbs.	Dimens	ions (US msn	nts.)	Volume	# Pieces:	
Other exemption - Write in:						l	Weight Lbs.	Depth	Width	Height	(Cube)	# Fieces.	
Is product repackaged? Is product sold by manufacturer's	e avalueiva dietributar?		es, was originet from mfr?	nal product purchased		Item/Each:	0.13	1.85	1.299	7.126	17.124847	1	
Has FDA granted waiver/exceptio	_			cumentation from FDA.		Box/Carton/Bundle	ı l						
l last 271 grantou maironoxeopus			,0, 4114011 401	Janion (11 11 11 11 11 11 11 11 11 11 11 11 11		Inner Pack:					0		
		GTIN AND HIBCC PRODUCT INFORMATION				Case:	5.6	12.598	7.165	6.378	575.70807	48	
Outside III II III							0.0	.2.000		5.57 6	3. 3.7 0007	.0	
Saleable Unit of Measure	Quantity 1	HIBCC	GTIN-	14 700109168	Unit of Use GTIN-14	Pallet:					0		
x Item/Each Box/Carton/Bundle/Inner Pack	1		00370	700 108 100									
x Case	48		10370	700109165			OST INFORMATION			WHOLESAL	ER USE ONL	.Y:	
Pallet													
						Regular Cost			Vendor #:	_			
						Invoice Cost (WAC	) (\$)	\$24.91	Whsl. Code Fineline Co				
						As of date:			Fineline Co	ue.			
									+				
		Attach copy of SAFETY DATA SHEET (SDS	S) or non haza	ard letter, PACKAGE INSE	ERT, LABEL AND PHOTO OF	PRODUCT PACKAGIN	G and BARCODE.		1				



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

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#### For Designated Drop Ship Only Products, Please Use Page 3

MAT	ERIAL HAZAI	RD CLASSIFICATION and TRANSPORTATION		
Is this product (check all that apply):  a. Cytotoxic?  b. CA Prop. 65 Carcinogen or Reproductive Toxicant?  Is the product a CA Prop 65 carcinogen?  Is the product a CA Prop 65 reproductive toxicant?  No  Does the product label bear a CA Prop 65 warning?  No		Organic Inorganic Steroid/Androgen	OS Hazard Classification  Corrosive Oxidizer Contact Hazard	
c. Contact Hazard? d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP?  Is this product regulated for shipment by DOT?	No No No	Aerosol Class; Identify NFPA Storage Level:  Is the product a NIOSH hazardous drug?  If yes, indicate which:	No	
(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	Haza EPA Hazardous Waste Code:	rdous Waste Identification	Waste Characteristics
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	No	REMS o Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:	r REGISTRY RESTRICTIONS No	
d. Packing Group e. Inhalation Hazard?  Is the product restricted for air shipment? If so, indicate restriction:  Passenger Cargo Passenger & Cargo		Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)	No	
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)		REMS:  REMS Program Manager Name:  Supplier Manages REMS registry exclusively:  Wholesale distributor support:  Provider Name:  Site Enrollment Number assigned by Supplier:		Phone:  DEA #: PCPDP#: NPI #:
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#  ADD'L STORAGE INFORMATION		Comments  Registry:  Registry Program Contact Name:  Comments		Phone:
Is the Product  Controlled Substance?  Controlled Substance Code  Controlled by State(s)?  No  Listed Chemical (List I or II)	No	RI	ETURN INSTRUCTIONS	
ARCOS Reportable?  Schedule No.  If yes, indicate which: Is it a scheduled listed chemical product?:  CLASS OF TRADE RESTRICTION:	No	Contact tel. # if product received damaged:  Is product returnable for credit:  URL/Link to returns policy:		
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Restricted to retail pharmacy only:  Restricted to hospital, clinics, and physician offices only:  Restricted from US territories? (explain in comments)  Comments:	Yes	Special regulations or returns requirements for this product in certain states?  If so, which states? Other requirements? Comments?		
MISC	CELLANEOU	S 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 Pr	oduct	Standard Order Receipt and Processing
Purchase orders may be accepted by:		Purchase order daily receipt cut off time by supplier
a. EDI		Cut off time:
b. Autofax Fax Number:		
c. Fax Number:		Shipping lead time of PO: Hours Days
d. Phone only Phone No.:		
e. Supplier Web Site only  Site Address:  Minimum Order Quantity:		Ships same day for next day receipt:  Ships for second day receipt:
Supplier's Customer Service Number:		Ships regular ground for 3-10 days receipt:
Contracted 3PL company / contact #: Name:		Chips regular ground for 5-10 days receipt.
Phone:		
Expedited Freight Charges or Other Designated Dr	op Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:		Overnight receipt available:
Drop Ship service fee billed with each order:		PO Receipt cut off time:
Drop Ship miscellaneous fees billed:		Days of week overnight is available: Monday
Comments:		Tuesday
		Wednesday
		Thursday
		Friday
		Priority Overnight receipt available:
Class of Trade Restriction:		PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and	nhysician offices	Saturday Overnight receipt available:
Restricted to retail pharmacy only:	priysician onices	PO Receipt Cut off time:
Restricted to hospital, clinics, and physician offices only:		Phone #
Restricted from US territories? (explain in comments)		Order receipt method:  Fax:  Fax#:
Comments:		EDI:
		Overnight Fees apply:
		Other fees apply:
Other Data Information Required to Proces	s PO:	Return Instructions
Patient Procedure Date:		Contact # if product is received damaged:
Physician Name:		Is product returnable for credit:
Physician/Clinic Phone #		URL/Link to returns policy:
Physician State License #		Special regulations or returns requirements for this product in certain states?
Physician/Clinic DEA #: Physician/Clinic Specialty:		If so, which states? Other requirements? Comments?
		il so, which states? Other requirements? Comments?
Miscellaneous Notes:		
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure?
		Is product order for restocking purposes?