

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

Version 2020						Introduction Type:	Open Stock	k		Final Version			Date:	7/10/	/2024
			PRODUCT INFORMA	TION						SPECIAL HAN	DLING AND STO	RAGE REQUI	REMENTS*		
Company Name: Xiromed LLC Application: ANDA a. 1									a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/AN	NDA/BLA (drug); PM/	A/510(k)(med device	ce):	210	034		•		, T	Temperature Range	Controlled Room	– between 20	and 25 C (68	° – 77° F)	
DUNS:	080228637				1					Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a		ne: Clobeta	sol Propionate							(write in)					
Selling Unit NDC:	70700-109-18		Unit of Use NDC:				0109182		N	Notes					
UDI			CVX Code:			MVX Code:									
Description:	Clobetasol Propiona	ate Cream USP, 0.0	5% 45gm Tube							s this product to be shipped				No	
Active Ingredient(s):		Clobetasol Propiona	ite							s this product to be shipped	to customers on (	ary ice?		No	•
										emperature excursion qu	estions:				
URL for Additional Product Inform Address:	180 Park Ave				1	Address 2: Suite	404			Name: Number:		Xiromed Qu 844-947-663			
City:	Florham Park				State:	NJ Zip:				Group E-mail:				oxiromed.co	om
Key Contact:	Xiromed Regulatory	,			Email:	usregulatory@xiror			`	Sroup L-mun.		OJ Quanty	Anomeag	All Officu.co	OIII
Phone Number:	844-947-6633				Fax:	862-286-0932			c. Special regul	ations for product in any	states?			No	_
Product Therapeutic Classificatio	on:								s	Special returns requiremen	s for this product?			No	•
	_				-										
	ADDITION	AL PRODUCT INF	ORMATION			PRODUCT DESC	RIPTION INFORMATI	ION	d. Store produc	ct (unit of sale) upright?					
The product is?			Is the Product	Direct-Ship O	nly					Protect product (unit of sa	ale) from light?				
a legend device?		No	Is the Product	Neither		Size:	45gm		e. Shelf life:					24	Months
if yes, enter class #		No	Orphan Drug Status				0.05%		ļ	nitial shelf life at launch (	if different):				Months
a product kit? if yes, list NDCs of		10	FDA Approval Status			Strength:	0.05%				ORDER INFOR	MATION			
component parts			. Dririppioral Glatag			B	Topical								
reverse numbered?		No				Dosage Form:			<u>.</u>	Jnit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present							Bottle		1 Box contai			
latex-free?		No	Not made with nat	ural rubber late	ex.	Product Shape:			<u> </u>	x Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes								Ampule					V
correctional institution block? opioid?		Yes No				Product Color:				Glass Tube		Wilnimum o	rder quantity		Yes
Cannabinoid?		No .	Country of Origin	Spain					<del> </del>	Vial Liquid Sgl					
If Unit Dose, is item bar coded to u		10	Country or Origin	орані		Product Imprint:			<del> </del>	Vial Liquid Multi		If Yes, how	many of wh	ch package t	type?
scanning?	·		Is this product covered u	nder the						Vial Powder Sql		48	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (	ΓAA)?	Yes					Vial Power Multi			Inner/Cartor	/Pack	
									<u>L</u>	Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS											
					Auth	orized Generic *If Aut	horized Generic, other	rocetion		DL	IARMACY ORDER	/ BILL LINIT			
	AD4			_	Auti		are not applicable	Section	Rec. sell unit to		ARMACT CREET				
I. Orange Book Rating: II. Generic Equivalent to What Bra	AB1	Temovate							Rec. sell unit to	1 Tube	1	x billing u	nit to pharm I Each	acy:	
ii. Generic Equivalent to What Bre	and:.	removate							(Write-in, e.g. 1		1		Gram		
		DRUG SUPPLY	CHAIN SECURITY ACT (	DSCSA) INFOR	RMATION				` , ,	,			Milliliter		
Does supplier meet DSCSA definition Is product exempt from DSCSA?		r?	Yes No	GLI	N:	0370700000007				ITEN	I AND PACKING I	NFORMATIO	N		
	-		NO	_							<b>D</b> !	(110	-4- \		
If yes, select exemption:										Weight Lbs.		ions (US msn Width		Volume (Cube)	# Pieces:
Other exemption - Write in: Is product repackaged?	L		No	If Y	es. was origi	nal product purchased	_		Item/Each:		Depth		Height		
Is product sold by manufacturer's	s exclusive distribute	or?	No		ect from mfr?			_		0.13	1.85	1.299	7.126	17.124847	1
Has FDA granted waiver/exceptio	on/exemption for pro-	duct?	No	If y	es, attach do	cumentation from FDA.			Box/Carton/Bui	ndle/				0	
				<del>-</del>					Inner Pack:					Ů	
		GTIN	AND HIBCC PRODUCT I	NFORMATION					Case:	6.6	15.748	8.268	6.378	830.44407	48
Saleable Unit of Measure	,	Quantity	HIBCC		GTIN-	14	Unit of Use GTIN-	_14	Pallet:						
x Item/Each	È	1	TIIDOO			700109182	OTHE OF CIGC CITIES		ll unct.					0	
Box/Carton/Bundle/Inner Pack	-											1	•	1	
x Case		48			10370	700109189				COST INFORMATION			WHOLESAL	ER USE ONL	.Y:
Pallet	_ [														
	┥ ├								Regular Cost	44 O) (C)	007.07	Vendor #:	ш.		
									Invoice Cost (W	VAC) (\$)	\$37.37	Whsl. Code Fineline Co			
	-								As of date:			- 1 111011110 00			
	<u> </u>								As of date:						
			Attach copy of SAFETY DA	ATA SHEET (SD	S) or non haza	ard letter, PACKAGE INSI	ERT, LABEL AND PHO	OTO OF PF		GING and BARCODE.					



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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? Does the product label bear a CA Prop 65 warning?	No No No	SDS Hazard Classification  Organic Corrosive Oxidizer  x Steroid/Androgen 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?				