

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

Version 2020						Introduction	n Type:	Open Stock			Final Version			Date:	7/10/	/2024
			PRODUCT INFORMAT	ION							SPECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name:	Xiromed LLC			000	704	Applic	cation:	ANDA	a. Temperat			erature range for t			···	
Application Number for NDA/AN		AA/510(k)(med devi	ice):	2097	/01						ature Range	Controlled Room	- between 20	and 25 C (68	3° – 77° F)	
DUNS: Proprietary Name (If Applicable) a	080228637 and Established Na	me: Clobet	asol Propionate								mperature Range F ite in)	Requirement				
Selling Unit NDC:	70700-106-17	ciobel	Unit of Use NDC:	1		UPC:	370700	106174		Notes						
UDI			CVX Code:			MVX Code:										
Description:	Clobetasol Propior	nate Ointment USP,	0.05% 60gm Tube									to customers on id			No	
Active Ingredient(s): Clobetasol Propionate																
URL for Additional Product Inform	nation:								b. contact it	Name:	ture excursion qu	estions.	Xiromed Qu	ality		
Address:	180 Park Ave					Address 2:	Suite 1			Number			844-947-663			
City: Key Contact:		Florham Park State: NJ Zip: 07932 Xiromed Regulatory Email: usregulatory@xiromed.com						Group E-mail:				US-Quality-Xiromed@xiromed.com				
Phone Number:	844-947-6633	1y			Fax:	862-286-0932		<u>eu.com</u>	c. Special re	gulations	for product in any	states?			No	
Product Therapeutic Classificatio	n:										eturns requirement				No	•
						2202110			_							
	ADDITIO	NAL PRODUCT INF				PRODUC	I DESCR	IPTION INFORMATION	d. Store pro		of sale) upright?					
The product is? a legend device?		No	Is the Product… Is the Product…	Direct-Ship Or Neither	nly			60gm	e. Shelf life:	Protect	product (unit of sa	ale) from light?			24	Months
if yes, enter class #		NO	Orphan Drug Status	Neither		Size:		oogin	e. onen me.	Initial sh	nelf life at launch (if different):			24	Months
a product kit?		No				Strength:		0.05%				,			ļ	
if yes, list NDCs of component parts			FDA Approval Status			_		Topical				ORDER INFORM	IATION			
reverse numbered?		No				Dosage Fo	orm:	Торісаі		Unit of S	Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present								Bottle		1 Box contai	ning 1 Tube		
latex-free?		No	Not made with nate	ral rubber late	ĸ.	Product Sh	hape:			x	Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free? correctional institution block?		Yes						-			Ampule Glass		Minimum o	rder quantity	17	Yes
opioid?		No				Product Co	olor:				Tube			uor quarity	,.	
Cannabinoid?		No	Country of Origin	Spain		Product Im	oprint:				Vial Liquid Sgl					
If Unit Dose, is item bar coded to u scanning?	init dose for hospital		Is this product covered ur	der the			•				Vial Liquid Multi Vial Powder Sql		If Yes, how 48	many of wh Each	ich package	type?
If Unit Dose, indicate NDC here:			Trade Agreements Act (T		Yes						Vial Power Multi		40	Inner/Cartor	n/Pack	
											Other: Write In			Case		
			FOR GENERIC DRUG PRO	DUCTS												
				Г	Auth	orized Generic	*If Autho	orized Generic, other sec	tion		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:				ר '				re not applicable	Rec. sell uni	it to custor	ner?		Rx billing u	nit to pharm	acv:	
II. Generic Equivalent to What Bra	and?:	Temovate								1 Tub	e]	x	Each		
			Y CHAIN SECURITY ACT (I		MATION				(Write-in, e.g	g. 1 Vial)				Gram Milliliter		
		DRUG SUPPL			MATION									1		
Does supplier meet DSCSA defini	ition of manufactu	rer?	Yes	GLN	4:	037070000007	7				ITEN	I AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			No	-								Dimerro	ons (US msn	ate)		
If yes, select exemption: Other exemption - Write in:											Weight Lbs.	Dimensi	ons (US msn Width	Height	Volume (Cube)	# Pieces:
Is product repackaged?			No			nal product purc	chased		Item/Each:		0.13	1.85	1.299	7.126	17.124847	1
Is product sold by manufacturer's			No No	_	ct from mfr?					Dame d'a d	0.10	1.00	1.200	1.120	11.124047	
Has FDA granted waiver/exceptio	n/exemption for pr	oduct?	INU	If ye	es, attach do	cumentation from	m FDA.		Box/Carton/ Inner Pack:	Bundle/					0	
		GTI	N AND HIBCC PRODUCT IN	IFORMATION					Case:		6.6	15.748	8.268	7.559	984.21554	48
Saleable Unit of Measure		Quantity	HIBCC		GTIN-	14		Unit of Use GTIN-14	Pallet:							
x Item/Each		1				700106174		Shit of Use GTIN-14							0	
Box/Carton/Bundle/Inner Pack							1									
X Case		48			10370	700106171	-			cos	T INFORMATION			WHOLESAL	ER USE ONL	Y:
Pallet	1						-		Regular Cos	st			Vendor #:			
									Invoice Cost)	\$48.00	Whsi. Code	#:		
	_						_				0/0/0004		Fineline Co	de:		
									As of date:		8/2/2021		-			
			Attach copy of SAFETY DA	TA SHEET (SDS	S) or non haza	ard letter, PACKA	GE INSER	RT, LABEL AND PHOTO	OF PRODUCT PAC	KAGING ar	nd BARCODE.		1			
*Please provide any additional inf	formation on page	2.						nated Drop Ship Only.		Signatu						

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

	ted Drop Ship Only Products, Please Use Page 3					
MATERIAL HAZ	ZARD 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	SDS Hazard Classification Organic Corrosive Inorganic Oxidizer X Steroid/Androgen Contact Hazard					
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? No (if yes, answer a-e below and provide SDS)	Aerosol Class; Identify NFPA Storage Level: Is the product a NIOSH hazardous drug? If yes, indicate which:					
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? No	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics					
	REMS or REGISTRY RESTRICTIONS					
Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Deaking Course	Is there a REMS on this product? No If Yes, is it managed with a pharmacy registry? Website URL:					
d. Packing Group e. Inhalation Hazard? No	Med Guide Required No					
Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	Limited Distribution Requirement No Comments / Details: (For example, iPledge program?)					
Is this a reportable quantity? No RQ Threshold: Is this a marine pollutant? <u>No</u> Is this product shipped utilizing an authorized DOT exception or Special Permit? <u>No</u> (if yes, identify method below) Limited Quantity Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4) Special Permit; DOT-SP Special Perovision (listed in Column 7 of 49 CFR 172.101);	REMS: Phone: Supplier Manages REMS registry exclusively: Phone: Wholesale distributor support: DEA #: Provider Name: DEA #: Site Enrollment Number assigned PCPDP#: by Supplier: NPI #:					
SP#	Registry:					
ADD'L STORAGE INFORMATION Is the Product	Registry Program Contact Name: Phone: Phone: Comments					
Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS					
Controlled by State(s)? No Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which: If yes, indicate which:	Contact tel. # if product received damaged: Is product returnable for credit: URL/Link to returns policy:					
Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only:	Special regulations or returns requirements for this product in certain states?					
Restricted from US territories? (explain in comments) Comments:	If so, which states? Other requirements? Comments?					
MISCELLANE	OUS NOTES and/or Image of Product Barcode:					



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Version 2020	FOR DESIGNATED DROP SHIP PRODUCT ONLY - if	not a designated drop ship, do not complete.						
Order Metho	od for Designated Drop Ship Product	Standard Order Receipt and Processing						
Purchase orders may be accepted by: a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #:	Fax Number: Fax Number: Phone No.: Site Address:	Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:						
Expedited Freight C	Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing						
Expedited freight fees billed with each of Drop Ship service fee billed with each of Drop Ship miscellaneous fees billed: Comments:		Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday						
(Class of Trade Restriction:	PO Receipt Cut off time:						
No restriction: Select YES if sold to retain Restricted to retail pharmacy only: Restricted to hospital, clinics, and physic Restricted from US territories? (explain in Comments:		Saturday Overnight receipt available: PO Receipt Cut off time: PO Receipt Cut off time: Phone: Order receipt method: Phone: Fax: EDI: Overnight Fees apply: Image: Constraint of the state of th						
Other Data	Information Required to Process PO:	Return Instructions						
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:		Contact # if product is 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:							
		ADDITIONAL INFORMATION Is product order for scheduled patient procedure? Is product order for restocking purposes?						