

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

Version 2021						Introduction	Type:	New Item		x Final Version			Date:	0/29/	/2023
			PRODUCT INFORMA	TION						SPECIAL HA	NDLING AND STOR	RAGE REQUIF	REMENTS*		
Company Name: XIROMED LLC Applicat				ation:	ANDA	a. Temperatu	a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/AN	IDA/BLA (drug); Pl	MA/510(k)(med device	e):	210	639				·	Temperature Range	Controlled Room		and 25 C (68	s° – 77° F)	
Medical Device Class, if applica	ble:														
DUNS:	080228637									Other Temperature Range	Requirement			ght container.	Store
Proprietary Name (If Applicable) a		ame: Betame	thasone Valerate Foam, 0.	12%						(write in)		between 15-	25° in dry pla	ce	
Selling Unit NDC:	70700-141-19		Unit of Use NDC:			UPC:	370700	0141199		Notes					
UDI			CVX Code:			MVX Code:									
Description:	Betamethasone \	/alerate 0.12% Foam -	50g Can							Is this product to be shipp				No	
Active Ingredient(s):		Betamethasone Vale	proto							Is this product to be shipp	ed to customers on o	Iry ice?		No	
Active ingredient(s):		betametriasone vale	erate						h Contact fo	r temperature excursion q	uestions:				
URL for Additional Product Inform	nation:	www.xiromed.co	m						D. 00111110110	Name:		VIPUL GANI	OHI		
Address:	180 Park Avenue					Address 2:	#101			Number:		9739537867			
City:	Florham Park				State:	NJ		07932		Group E-mail:		us.quality@e	xeltis.com;		
Key Contact:	DAVID HERNAN	DEZ			Email:		NDEZ@	XIROMED.COM							-
Phone Number:	844-947-6633	1			Fax:	862-286-0932			c. Special reg	gulations for product in an	-			No	
Product Therapeutic Classification	on:	topical corticosteroid								Special returns requireme	nts for this product?			No	
	ADDIT	IONAL PRODUCT INF	OPMATION			PRODUCT	DESCRI	IPTION INFORMATION	d C4	uct (unit of sale) upright?				Yes	1
	ADDITI	IONAL FRODUCT IN		Discret Ohio O		FRODUCT	DESCRI	IF HON INI OKWATION	u. Store prou	· · · -]
The product is? a legend device?		No	Is the Product Is the Product	Direct-Ship O Neither	riiy			50g Can	e. Shelf life:	Protect product (unit of	sale) from light?			No 24	Months
if yes, enter class #		INO	Orphan Drug Status	rveiulei		Size:		30g Call	e. Sileli ille.	Initial shelf life at launch	(if different):			24	Months
a product kit?		No	Orphun Drug Otatus					0.12%		miliai siicii ilic at laalicii	(ii dilicicity).			24	INIOIILIIS
if yes, list NDCs of		1112	FDA Approval Status			Strength:					ORDER INFORM	MATION			
component parts						Dosage For	m.	Foam							
reverse numbered?		No				Dosage i on				Unit of Sale		What is the			
co-licensed?		No	Allergens Present							Bottle		1 Box contai			
latex-free? preservative-free?		Yes Yes				Product Sha	ape:	N/A		X Box/Carton Ampule		(Write-in, e.	g. 1 Box of 1	0 Vials)	
correctional institution block?		No						White		Glass		Minimum or	der quantity	2	Yes
opioid?		No				Product Col	lor:			Tube			uo. quuiitty	•	
Cannabinoid?		No	Country of Origin	Spain		Product Imp	arint.	N/A		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for					Product iiiip	Jilit.			Vial Liquid Multi				ch package t	type?
hospital scanning?			Is this product covered u							Vial Powder Sql			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (TAA)?	Yes					Vial Power Multi			Inner/Carton	/Pack	
			FOR GENERIC DRUG PR	ODUOTO						Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCIS											
					Au	thorized Generic	*If Auth	horized Generic, other	PHARMACY ORDER / BILL UNIT						
I. Orange Book Rating:	AB						section	n fields are not applicable	Rec. sell unit to customer? Rx billing unit to pharmacy:						
II. Generic Equivalent to What Bra		LUXIQ								containing 1 Canister		X	Each	,-	
•									(Write-in, e.g.	. 1 Vial)	_		Gram		
		DRUG SUPPLY	Y CHAIN SECURITY ACT (DSCSA) INFOR	MATION								Milliliter		
Does supplier meet DSCSA defini	ition of manufactur	ror?	Yes		GLN:	0370700000007				ITE	M AND PACKING I	NEORMATION			
Is product exempt from DSCSA?	inon or manuractu	1011	No		OLIN.	337070000007				- 1115		ormiziTiOi			
If yes, select exemption:					GCP:						Dimensi	ons (US msm	ts.)	Volume	Saleable #
Other exemption - Write in:										Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was or	riginal product pur	rchased		Item/Each:	0.882		1.575		13.673205	1
Is product sold by manufacturer's			No		direct from m	nfr?					1.575	1.375	5.512	13.073205	
Has FDA granted waiver/exception		roduct?	No		Provide sour	ce manufacturer fo	or repacl	kaged product	Box/Carton/E	Bundle/				0	
If yes, attach documentation fro	m FDA.								Inner Pack:						
		GTIN	I AND HIBCC PRODUCT II	NEORMATION					Case:	34.471	6.693	1.89	1.862	23.553872	32
		GIII	TAND HIBEC PRODUCT II	NI ORMATION					Pallet:						
Saleable Unit of Measure	5	Saleable Quantity	HIBCC		GTI	N-14		Unit of Use GTIN-14	l unct.					0	
X Item/Each		1				70700141199									
Box/Carton/Bundle/Inner Pack										COST INFORMATION		1	WHOLESALI	ER USE ONL	.Y:
X Case		32			103	70700141196									
Pallet									Regular Cost		AT :	Vendor #:			
	_								Invoice Cost	(WAC) (\$)	\$74.83	Whsl. Code Fineline Code			
									As of date:			I memie Co	ıc.		
									, 15 5. dato.						
	_						_								
*Please provide any additional inf			Attach copy of SAFETY DA	ATA SHEET (SD	S) or non haza	rd letter, PACKAGE	E INSER	T, LABEL AND PHOTO OF F	RODUCT PACK	AGING and BARCODE.					



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

Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

	MATERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply):							
a. Cytotoxic?	No	SDS Hazard Classification					
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?							
Is the product a CA Prop 65 carcinogen?	No	Organic	Corrosive				
Is the product a CA Prop 65 reproductive toxicant?	No	Inorganic	Oxidizer				
Does the product label bear a CA Prop 65 warning?	No	Steroid/Androgen	Contact Hazard				
bocs the product laber bear a OAT Top 05 warning:	140	Steroid/Androgen	Contact Hazard				
c. Contact Hazard?	No	Does the product have an Aerosol class? If yes,	Yes				
d. Does this product require special clean-up instructions?	No	identify NFPA Storage Level:					
(If yes, attach SDS with special instructions.)	140	NFPA Storage Level:	Level 1				
e. Does the product contain DEHP?		Till 177 Glorage 2076.	2010. 1				
·							
Is this product regulated for shipment by DOT?	Yes	Is the product a NIOSH hazardous drug?	No				
(if yes, answer a-e below and provide SDS)		If yes, indicate which:					
a. UN/Identification Number b. Proper Shipping Name 1950 Aerosols, flammable							
1 11 3		Hazardous Waste Identification					
c. DOT Hazard Class d. Packing Group 2.1 N/A		Hazaruous waste tuentineation					
e. Inhalation Hazard?	Yes	EPA Hazardous Waste Code:		Waste Characteristics			
		LI A Hazardous Waste Code.		Waste Criaracteristics			
Is this product regulated for shipment by IATA?	Yes		DECISEDY DESERVATIONS				
(if yes, answer a-e below and provide SDS)		REMS o	r REGISTRY RESTRICTIONS				
a. UN/Identification Number 1950							
b. Proper Shipping Name Aerosols, flammable		Is there a REMS on this product?	No				
c. DOT Hazard Class d. Packing Group N/A		If Yes, is it managed with a pharmacy registry?					
arr animg creap	V	Website URL:					
e. Inhalation Hazard?	Yes						
Is the product restricted for air shipment? If so, indicate restric	tion:	Med Guide Required					
Passenger		Limited Distribution Requirement					
Cargo		Comments / Details: (For example, iPledge program?)					
Passenger & Cargo							
Is this a reportable quantity? No		REMS:					
RQ Threshold:		REMS Program Manager Name:		Phone:			
Is this a marine pollutant? No		Supplier Manages REMS registry exclusively:					
Is this product shipped utilizing an authorized DOT exception of	r Special Permit?	Wholesale distributor support:					
No (if yes, identify method below)		Provider Name:		DEA #:			
Limited Quantity		Site Enrollment Number assigned		NCPDP#:			
Consumer Commodity, ORM-D		by Supplier:		NPI #:			
Small Quantity (49 CFR 173.4)							
Special Permit; DOT-SP	04):	Comments					
Special Provision (listed in Column 7 of 49 CFR 172.1	01);						
SP#		Registry:					
		Registry Program Contact Name:		Phone:			
ADD'L STORAGE INFORM	ATION	Comments					
Is the Product							
Controlled Substance? No Controlled Subst		RI	ETURN INSTRUCTIONS				
Controlled by State(s)? Listed Chemical							
ARCOS Reportable? If yes, indicate v	which:	Contact tel. # if product received damaged:					
Schedule No. Is it a scheduled	d listed chemical product?:	Is product returnable for credit:					
CLASS OF TRADE RESTRI	CTION:	URL/Link to returns policy:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician of	fines						
Restricted to retail pharmacy only:		Special regulations or returns requirements for this					
Restricted to hospital, clinics, and physician offices only:		product in certain states?					
Restricted from US territories? (explain in comments)		If so, which states? Other requirements? Comments?					
Comments:							
	MICCEL LANGO	US NOTES and/or Image of Breduct Bereads					
	WISCELLANEO	US NOTES and/or Image of Product Barcode:					



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

Version 2021

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Desig	gnated Drop Ship Product	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	Fax Number:	Shipping lead time of PO: Hours Days					
d. Phone only	Phone No.:	China cama day far nayt day receipts					
e. Supplier Web Site only Minimum Order Quantity:	Site Address:	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:		Ships regular ground for 3-10 days receipt.					
Phone:							
	Other Designated Drop 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:		Days of week overnight is available: Tuesday					
Comments.		Wednesday					
		Thursday					
		Friday					
		Priority Overnight receipt available:					
Class of Tro	de Restriction:						
		PO Receipt Cut off time:					
No restriction: Select YES if sold to retail pharmacy,	hospitals, clinics and physician offices	Saturday Overnight receipt available:	_				
Restricted to retail pharmacy only:		PO Receipt Cut off time:	_				
Restricted to hospital, clinics, and physician offices o Restricted from US territories? (explain in comments		Order receipt method: Phone: Phone #: Fax: Fax #:	-				
Comments:	5)	EDI:					
Comments.		Overnight Fees apply:					
		Other fees apply:					
Other Data Information	n Required to Process 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 #							
Physician/Clinic DEA #:		Special regulations or returns requirements for this product in certain states?					
Physician/Clinic Specialty:		If so, which states? Other requirements? Comments?					
Miscelland	neous Notes:						
		ADDITIONAL INFORMATION					
		Is product order for scheduled patient procedure?					
		Is product order for restocking purposes?					