

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

						Introduction T	уре.	New Item		x Final Version			Date:	6/29/	2023
			PRODUCT INFORMA	TION						SPECIAL HAN	DLING AND STOR	AGE REQUI	EMENTS*		
Company Name:	XIROMED LLC					Applicat	tion:	ANDA	a. Temperatu	re - Indicate the USP tempe	rature range for th	nis product.			
Application Number for NDA/AN	IDA/BLA (drug); PI	MA/510(k)(med devic	:e):	210	639				11	Temperature Range	Controlled Room -	- between 20	and 25 C (68	° – 77° F)	
Medical Device Class, if applical	ble:														
DUNS:	080228637									Other Temperature Range F	equirement			ht container.	Store
Proprietary Name (If Applicable) a		ame: Betam	ethasone Valerate Foam, 0.	12%						(write in)		between 15-	5° in dry pla	ce	
Selling Unit NDC:	70700-141-19		Unit of Use NDC:			UPC:	370700141199			Notes					
UDI			CVX Code:			MVX Code:			-						
Description:	Betamethasone V	/alerate 0.12% Foam -	- 50g Can							Is this product to be shipped				No	
									-	Is this product to be shipped	to customers on d	ry ice?		No	
Active Ingredient(s):		Betamethasone Val	erate						h Contact for	r temperature excursion que	otions:				
URL for Additional Product Inform	nation:	www.xiromed.co	am .						D. Contact for	Name:	stions.	Xiromed Qua	lity		
Address:	180 Park Avenue		<u> </u>			Address 2:	#101		1	Number:		9739537867	,		
City:	Florham Park				State:	NJ	Zip: 07932			Group E-mail:		US-Quality	-Xiromed@	xiromed.co	<u>om</u>
Key Contact:	Xiromed Regulato	ory			Email:	usregulatory@	xiromed.com								
Phone Number:	844-947-6633				Fax:	862-286-0932			c. Special reg	julations for product in any				No	
Product Therapeutic Classificatio	on:	topical corticosteroid	d							Special returns requirement	for this product?			No	
	ADDITI	ONAL PRODUCT IN	FORMATION			PRODUCT	DESCRIPTION IN	FORMATION	1						ı
	ADDITI	IONAL PRODUCT INF				PRODUCTI	DESCRIPTION IN	FORMATION	d. Store prod	uct (unit of sale) upright?				Yes	
The product is?			Is the Product	Direct-Ship O	nly					Protect product (unit of sa	le) from light?			No	
a legend device? if yes, enter class #		No	Is the Product Orphan Drug Status	Neither		Size:	50g Can		e. Shelf life:	Initial shelf life at launch (i	f -1166			24	Months Months
a product kit?		No	Orphan Drug Status				0.12%			initial shell life at launch (i	ramerent):			24	Wonths
if yes, list NDCs of		140	FDA Approval Status			Strength:	0.1270				ORDER INFORM	ATION			
component parts						Danama Farm	Foam								
reverse numbered?	-	No				Dosage Forn	n:			Unit of Sale		What is the			
co-licensed?		No	Allergens Present							Bottle		1 Box contai			
latex-free?		Yes				Product Sha	pe: N/A			X Box/Carton		(Write-in, e.	j. 1 Box of 10) Vials)	
preservative-free? correctional institution block?		Yes					White			Ampule Glass		Minimum or	dor augntitu	.	Yes
opioid?		No No				Product Cold	or:			Tube		Minimum or	uer quantity	'	res
Cannabinoid?		No	Country of Origin	Spain			N/A			Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for		, ,			Product Impi	rint:			Vial Liquid Multi		If Yes, how	nany of whi	ch package t	type?
hospital scanning?			Is this product covered u							Vial Powder Sql		32	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (TAA)?	Yes					Vial Power Multi			Inner/Carton	/Pack	
]	Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS											
						thorized Generic	*If Authorized Ge			DU	ARMACY ORDER	/ PILL LINIT			
	AD				Au	monzed Generic	section fields are		Dec. and south		ARMACT ORDER				
I. Orange Book Rating: II. Generic Equivalent to What Bra	AB	LUXIQ								to customer? containing 1 Canister		Rx billing u	Each	icy:	
ii. Generic Equivalent to what Bra	and?:	LUXIQ							(Write-in, e.g.			_ X	Gram		
		DRUG SUPPL	Y CHAIN SECURITY ACT	(DSCSA) INFOR	MATION				(**************************************	· · · · · · · · ·			Milliliter		
		-													
Does supplier meet DSCSA defini	ition of manufactu	rer?	Yes		GLN:	0370700000007				ITEM	AND PACKING IN	IFORMATION			
Is product exempt from DSCSA?			No												
					GCP:					Weight Lbs.		ons (US msm	•	Volume	Saleable #
If yes, select exemption:											Depth	Width	Height	(Cube)	Pieces
Other exemption - Write in:			N-										5.512	13.673205	1
Other exemption - Write in: Is product repackaged?	a avaluaiva diatribu	utor2	No			iginal product purd	chased		Item/Each:	0.882	1.575	1.575	0.012		
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's			No		direct from m	ifr?		aduct			1.575	1.575	5.512		
Other exemption - Write in: Is product repackaged?	n/exemption for p				direct from m			oduct	Item/Each: Box/Carton/B Inner Pack:		1.575	1.575	5.512	0	
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio	n/exemption for p	roduct?	No No		direct from m	ifr?		oduct	Box/Carton/B	Sundle/					22
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio	n/exemption for p	roduct?	No		direct from m	ifr?		oduct	Box/Carton/B Inner Pack: Case:		1.575 6.693	1.575	1.862	23.553872	32
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation from	on/exemption for pi m FDA.	roduct?	No No N AND HIBCC PRODUCT I		direct from m Provide sour	rfr? ce manufacturer fo	or repackaged pro		Box/Carton/B	Sundle/					32
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation from	on/exemption for pi m FDA.	roduct?	No No		direct from m Provide sour	off? ce manufacturer fo	or repackaged pro	bduct Jse GTIN-14	Box/Carton/B Inner Pack: Case:	Sundle/				23.553872	32
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation from Saleable Unit of Measure X Item/Each	on/exemption for pi m FDA.	roduct?	No No N AND HIBCC PRODUCT I		direct from m Provide sour	rfr? ce manufacturer fo	or repackaged pro		Box/Carton/B Inner Pack: Case:	34.471		1.89	1.862	23.553872	
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation froi Saleable Unit of Measure X Item/Each Box/Carton/Bundle/Inner Pack	on/exemption for pi m FDA.	GTII Saleable Quantity	No No N AND HIBCC PRODUCT I		direct from m Provide sour	oce manufacturer for N-14	or repackaged pro		Box/Carton/B Inner Pack: Case:	Sundle/		1.89	1.862	23.553872	
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation from Saleable Unit of Measure X Item/Each	on/exemption for pi m FDA.	roduct?	No No N AND HIBCC PRODUCT I		direct from m Provide sour	off? ce manufacturer fo	or repackaged pro		Box/Carton/B Inner Pack: Case:	34.471 COST INFORMATION		1.89	1.862	23.553872	
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation froi Saleable Unit of Measure X Item/Each BoxCarton/Bundle/Inner Pack X Case	on/exemption for pi m FDA.	GTII Saleable Quantity	No No N AND HIBCC PRODUCT I		direct from m Provide sour	oce manufacturer for N-14	or repackaged pro		Box/Carton/B Inner Pack: Case: Pallet:	34.471 COST INFORMATION	6.693	1.89	1.862 VHOLESALE	23.553872	
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation froi Saleable Unit of Measure X Item/Each BoxCarton/Bundle/Inner Pack X Case	on/exemption for pi m FDA.	GTII Saleable Quantity	No No N AND HIBCC PRODUCT I		direct from m Provide sour	oce manufacturer for N-14	or repackaged pro		Box/Carton/B Inner Pack: Case: Pallet: Regular Cost Invoice Cost	34.471 COST INFORMATION	6.693	1.89 Vendor #:	1.862 VHOLESALE	23.553872	
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation froi Saleable Unit of Measure X Item/Each BoxCarton/Bundle/Inner Pack X Case	on/exemption for pi m FDA.	GTII Saleable Quantity	No No N AND HIBCC PRODUCT I		direct from m Provide sour	oce manufacturer for N-14	or repackaged pro		Box/Carton/B Inner Pack: Case: Pallet:	34.471 COST INFORMATION	6.693	1.89 Vendor #: Whsl. Code	1.862 VHOLESALE	23.553872	
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation froi Saleable Unit of Measure X Item/Each BoxCarton/Bundle/Inner Pack X Case	on/exemption for pi m FDA.	GTII Saleable Quantity	No No N AND HIBCC PRODUCT I		direct from m Provide sour	oce manufacturer for N-14	or repackaged pro		Box/Carton/B Inner Pack: Case: Pallet: Regular Cost Invoice Cost	34.471 COST INFORMATION	6.693	1.89 Vendor #: Whsl. Code	1.862 VHOLESALE	23.553872	
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation froi Saleable Unit of Measure X Item/Each BoxCarton/Bundle/Inner Pack X Case	on/exemption for pi m FDA.	GTII Saleable Quantity	No No N AND HIBCC PRODUCT I	NFORMATION	GTI 003	N-14 70700141199	Unit of U	Jse GTIN-14	Box/Carton/B Inner Pack: Case: Pallet: Regular Cost Invoice Cost As of date:	COST INFORMATION (WAC) (\$)	6.693	1.89 Vendor #: Whsl. Code	1.862 VHOLESALE	23.553872	



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Version 2021 For Designated Drop Ship Only Products, Please Use Page 3

	MAT	ERIAL HAZ	ZARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply):								
a. Cytotoxic?			SDS Hazard Classification					
				30 1142414 314331116411311				
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?				¬ • ·				
Is the product a CA Prop 65 carcinogen?			Organic	Corrosive				
Is the product a CA Prop 65 rep		No	Inorganic	Oxidizer				
Does the product label bear a CA Prop 65 warning?			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?			identify NFPA Storage Level:					
(If yes, attach SDS with			NFPA Storage Level:	Level 1				
e. Does the product contain DEHP?	,							
'								
Is this product regulated for shipment by	y DOT?	Yes	Is the product a NIOSH hazardous drug?	No				
(if yes, answer a-e below and provide			If yes, indicate which:					
 a. UN/Identification Number 	1950							
b. Proper Shipping Name	Proper Shipping Name Aerosols, flammable							
c. DOT Hazard Class	2.1		Hazardous Waste Identification					
d. Packing Group	N/A							
e. Inhalation Hazard?	Yes		EPA Hazardous Waste Code:		Waste Characteristics			
	L. IATAO							
Is this product regulated for shipment b		Yes	PENO	PEGISTRY PESTRICTIONS				
(if yes, answer a-e below and provide			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	2.1		If Yes, is it managed with a pharmacy registry?					
d. Packing Group	N/A		Website URL:					
e. Inhalation Hazard?		Yes						
Is the product restricted for air shipmen	t? If so indicate restriction:		Med Guide Required					
Passenger	in so, maisats recursions		Limited Distribution Requirement					
Cargo			Comments / Details: (For example, iPledge program?)					
Passenger & Cargo			Ochiments / Details. (For example, if leage programs)					
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 auth	orized DOT exception or Special Permit?		Wholesale distributor support:					
No (if yes, identify method	d 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			Comments					
Special Provision (listed in Col	lumn 7 of 49 CFR 172.101):							
SP#			Registry:					
OI #					Dhanai			
ADD	D'L STORAGE INFORMATION		Registry Program Contact Name:		Phone:			
ADL	D L STURAGE INFURMATION		Comments					
Is the Product								
Controlled Substance? No	Controlled Substance Code		R	ETURN INSTRUCTIONS				
Controlled by State(s)?	Listed Chemical (List I or II)							
ARCOS Reportable?	If yes, indicate which:		Contact tel. # if product received damaged:					
Schedule No.	Is it a scheduled listed chemical product?:		Is product returnable for credit:					
SI A	SS OF TRADE RESTRICTION:							
	_		URL/Link to returns policy:					
No restriction: Select YES if sold to retail pharmacy	y, hospitals, clinics and physician offices							
Restricted to retail pharmacy only:			Special regulations or returns requirements for this					
, , ,								
Restricted to hospital, clinics, and phys	•		product in certain states?					
Restricted from US territories? (explain	in comments)		If so, which states? Other requirements? Comments?					
Comments:								
	MIG	CELLANE	OUS NOTES and/or Image of Product Barcode:					
	MIS	AINE	555 NOTES and of image of Floudet Balcode.					



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 Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI b. Autofax Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time:
c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Fax Number: Site Address: Site Address: Name:	Shipping lead time of PO: Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:
Phone:	
Expedited Freight Charges or Other Designated Drop Ship Fees: Expedited freight fees billed with each order:	Overnight and Priority Overnight PO Processing Overnight receipt available:
Drop Ship service fee billed with each order:	PO Receipt cut off time:
Drop Ship miscellaneous fees billed: Comments:	Days of week overnight is available: Monday 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 physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
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: Miscellaneous Notes:	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?
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure? Is product order for restocking purposes?