

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

Version 2020						Introduction Type:	Post Launch Change]	Final Version			Date:	7/10/	2024
			PRODUCT INFORMA	TION					SPECIAL HAN	NDLING 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	A/BLA (drug); PMA/510(k)(med device): 212612						Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)							
DUNS:	080228637							Other T	emperature Range I	Requirement				
Proprietary Name (If Applicable) a		GLYCOP'	YRROLATE			l une lesse			vrite in)		-			
Selling Unit NDC:	70700-167-25		Unit of Use NDC: CVX Code:			UPC: 37070 MVX Code:	00167250	Notes						
						MVX OCCC.							NI.	
Description:	Glycopyrrolate Injection,	USP T mg/smL	wulliple Dose viai						product to be shipped product to be shipped				No No	
Active Ingredient(s):	GLYC	OPYRROLATE												
						b. Contact for temperature excursion questions: Name: Xiromed Quality								
URL for Additional Product Inform Address:	180 Park Ave					Address 2: Suite	101	Name: Numbe			Xiromed Qua 844-947-663			
City:	Florham Park				State: NJ Zip: 07932			Group E-mail:					xiromed.co	m
Key Contact:	Xiromed Regulatory				Email: usregulatory@xiromed.com						ob quality Anonicate Anonicatedin			
Phone Number:	844-947-6633				Fax: 862-286-0932			c. Special regulations for product in any states?				No		
Product Therapeutic Classificatio	n:							Special	returns requirement	ts for this product?			No	
	ADDITIONAL P		DMATION				RIPTION INFORMATION		- (l -) l - h - (-)				N/s s	
	ADDITIONAL P	RODUCT INFO				PRODUCT DESC	RIPTION INFORMATION	d. Store product (unit					Yes	
The product is? a legend device?	No		Is the Product Is the Product	Direct-Ship On Neither	ly		25 x 5 mL Multiple Dose	e. Shelf life:	t product (unit of sa	ale) from light?			Yes 24	Months
if yes, enter class #	NO		Orphan Drug Status			Size:	Vials		helf life at launch (if different):			24	Months
a product kit?	No					Strength:	0.2MG/ML			,				
if yes, list NDCs of			FDA Approval Status			ou engin.		-		ORDER INFORI	MATION			
component parts reverse numbered?	No					Dosage Form:	INJECTABLE	Unit of	Sala		What is the I	NDC selling	unit?	
co-licensed?	No		Allergens Present					Onit of	Bottle		1 Box of 25 \		unit.	
latex-free?	Yes					Product Shape:		x	Box/Carton		(Write-in, e.g) Vials)	
preservative-free?	No					Product Shape.			Ampule					
correctional institution block?	Yes					Product Color:			Glass		Minimum or	der quantity	?	Yes
opioid? Cannabinoid?	<u>No</u> No		Country of Origin	India					Tube Vial Liquid Sgl					
If Unit Dose, is item bar coded to u			Country of Origin	India		Product Imprint:			Vial Liquid Ogl		If Yes, how r	nanv of whi	ch package ty	vpe?
hospital scanning?			Is this product covered u						Vial Powder Sql			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (FAA)? <u>I</u>	No				Vial Power Multi			Inner/Carton	/Pack	
									Other: Write In			Case		
		ŀ	FOR GENERIC DRUG PF	RODUCTS										
				Г	Autho	orized Generic *If Au	thorized Generic, other section		PI	HARMACY ORDER	R / BILL UNIT			
I. Orange Book Rating:	AP						are not applicable	Rec. sell unit to customer? Rx billing unit to pharmacy:						
II. Generic Equivalent to What Bra		ul®						1 Vial x Each						
								(Write-in, e.g. 1 Vial)				Gram		
	L	DRUG SUPPLY	CHAIN SECURITY ACT	(DSCSA) INFORI	MATION							Milliliter		
Does supplier meet DSCSA defini	tion of manufacturer?		Yes	GLN		0370700000007		т — ———	ITE	M AND PACKING I	NFORMATION			
Is product exempt from DSCSA?			No	_ 010	•									
If yes, select exemption:				_				-		Dimens	ions (US msm	ts.)	Volume	
Other exemption - Write in:									Weight Lbs.	Depth	Width	Height	(Cube)	# Pieces:
Is product repackaged?			No			al product purchased		Item/Each:	0.8	4.72	4.72	1.97	43.888448	1
Is product sold by manufacturer's			No No		ct from mfr?			Box/Carton/Bundle/				-		
Has FDA granted waiver/exceptio	n/exemption for product?	·	INO	IT yes	s, attach doc	umentation from FDA.		Inner Pack:					0	
		GTIN	AND HIBCC PRODUCT	INFORMATION				Case:	11.4219	10.039	10.039	6.496	654.67676	12
								1.	11.4219	10.039	10.039	0.490	034.07070	12
Saleable Unit of Measure	Quant 1		HIBCC		GTIN-1	14 700167250	Unit of Use GTIN-14	Pallet:					0	
X Item/Each Box/Carton/Bundle/Inner Pack		<u> </u>			00370	700167250								
X Case	1:	2			20370	700167254		CO	ST INFORMATION			WHOLESAL	ER USE ONL'	Y:
Pallet	_													
								Regular Cost			Vendor #:			
	┥ ┝━							Invoice Cost (WAC) (5)	\$274.00	Whsl. Code Fineline Cod			
	1 -							As of date:			i menne cot			
			Attach copy of SAFETY D	ATA SHEET (SD	S) or non haz	ard letter, PACKAGE INS	ERT, LABEL AND PHOTO OF	PRODUCT PACKAGING a	Ind BARCODE.					
*Please provide any additional inf	ormation on page 2.					See new p. 3 for Desig	gnated Drop Ship Only.	Signate	ure:					



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Version 2020 For Designated 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 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	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics							
e. Inhalation Hazard? 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. Packing Group	REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? No If Yes, is it managed with a pharmacy registry? No Website URL: Image: Color of the pharmacy is a pharmacy in the pharmacy in the pharmacy is a pharmacy in the pharmacy in the pharmacy is a pharmacy in the pharmacy in the pharmacy is a pharmacy in the pharmacy in the pharmacy in the pharmacy is a pharmacy in the pharmacy in the pharmacy in the pharmacy is a pharmacy in the pharmacy in the pharmacy in the pharmacy is a pharmacy in the pharmacy is a pharmacy in the pharmacy in							
e. Inhalation Hazard? Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	Med Guide Required No Limited Distribution Requirement No Comments / Details: (For example, iPledge program?) No							
Is this a reportable quantity? No RQ Threshold: No 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) 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: Provider Name: Provider Name: DEA #: Site Enrollment Number assigned PCPDP#: by Supplier: NPI #:							
ADD'L STORAGE INFORMATION	Registry: Phone: Registry Program Contact Name: Phone: Comments Phone:							
Is the Product								
Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which: If yes, indicate which:	RETURN INSTRUCTIONS Contact tel. # if product received damaged: Is product returnable for credit: URL/Link to returns policy:							
Restricted to hospital, clinics, and physician offices only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?							
Comments.								
MISCELLANEC	OUS NOTES and/or Image of Product Barcode:							



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Version 2020	FOR DESIGNATED DROP SHIP PRODUCT ONLY - i	f not a designated drop ship, do not complete.				
Order Meth	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	Fax Number: 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: Ships same day for next day receipt:	Days			
Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Expedited Freight (Name: Phone: Charges or Other Designated Drop Ship Fees:	Ships for second day receipt: Ships regular ground for 3-10 days receipt: Overnight and Priority Overnight PO Processing				
Expedited freight fees billed with each o	rder:	Overnight receipt available:				
Drop Ship service fee billed with each o	rder:	PO Receipt cut off time:	_			
Drop Ship miscellaneous fees billed: Comments:			londay luesday Vednesday hursday iriday			
		Priority Overnight receipt available:				
No restriction: Select YES if sold to retain Restricted to retail pharmacy only: Restricted to hospital, clinics, and physic Restricted from US territories? (explain Comments:	in comments)	PO Receipt Cut off time: Image: Saturday Overnight receipt available: PO Receipt Cut off time: PO Receipt Cut off time: Order receipt method: Phone: Fax: Fax #: EDI: Image: Saturday Overnight Fees apply: Other fees apply: Image: Saturday Overnight 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:		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?				