

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

Version 2020				Introduction Type:	New Item]	Final Version			Date:	7/10/2	2024
		PRODUCT INFORMATION					SPECIAL HAN	IDLING AND STOP	RAGE REQUI	REMENTS*		
Company Name:	Xiromed LLC			Application:	ANDA	a. Temperature – In	dicate the USP tempe					
Application Number for NDA/AN	NDA/BLA (drug); PMA/510(k)(med devi	ice): 2	212612		•	Temp	erature Range	Controlled Room -	- between 20	and 25 C (68	– 77° F)	
DUNS:	080228637						Temperature Range F	Requirement				
Proprietary Name (If Applicable) a	and Established Name: GLYC 70700-168-23	OPYRROLATE					(write in)					
Selling Unit NDC: UDI	70700-168-23	Unit of Use NDC: CVX Code:		UPC: 37070	0168233	Notes	•					
				MVX Couc.		1.444	and the first state of the second state of the				No	
Description:	Glycopyrrolate Injection, USP 4 mg/20	J TIL Multiple Dose Viai					product to be shipped product to be shipped				No	
Active Ingredient(s):	GLYCOPYRROLA	ATE				1	· · · · · · · · · · · · · · · · · · ·		.,			
							erature excursion que	estions:				
URL for Additional Product Inform Address:	180 Park Ave			Address 2: Suite	101	Name			Xiromed Qua 844-947-663			
City:	Florham Park		State:	Address 2: Suite ' NJ Zip:	07932	Numb	per: p E-mail:				xiromed.co	m
Key Contact:	Xiromed Regulatory		Email:	usregulatory@xirom			p E-mail.		05 Quanty	Anomeula	XII OIIICU.CO	
Phone Number:	844-947-6633		Fax:	862-286-0932		c. Special regulation	ns for product in any	states?			No	
Product Therapeutic Classification	on:					Speci	al returns requirement	s for this product?			No	
	ADDITIONAL PRODUCT IN			PRODUCT DESCI	RIPTION INFORMATION	d. Store product (un					Yes	
The product is? a legend device?	Νο	Is the Product Direct-Ship Is the Product Neither	Only		10 x 20 mL Multiple Dose	e. Shelf life:	ct product (unit of sa	le) from light?			Yes 24	Months
if yes, enter class #	NO	Orphan Drug Status		Size:	Vials		shelf life at launch (i	f different):			24	Months
a product kit?	No			Strength:	0.2MG/ML			,-				
if yes, list NDCs of		FDA Approval Status		Strength.				ORDER INFORM	NATION			
component parts reverse numbered?	No			Dosage Form:	INJECTABLE		of Sale		What is the		unit?	
co-licensed?	No	Allergens Present				Unit C	Bottle		1 Box of 10			
latex-free?	Yes	3		Product Shape:		x				g. 1 Box of 10	Vials)	
preservative-free?	No			Product Shape:			Ampule					
correctional institution block?				Product Color:			Glass		Minimum or	der quantity	?	No
opioid? Cannabinoid?	No No	Country of Origin India					Tube Vial Liquid Sgl					
If Unit Dose, is item bar coded to u		obulity of origin		Product Imprint:			Vial Liquid Ogl		If Yes, how	nany of whi	ch package ty	/pe?
hospital scanning?		Is this product covered under the					Vial Powder Sql			Each		
If Unit Dose, indicate NDC here:		Trade Agreements Act (TAA)?	No				Vial Power Multi			Inner/Carton	/Pack	
							Other: Write In			Case		
		FOR GENERIC DRUG PRODUCTS										
			Auth	orized Generic *If Aut	norized Generic, other section		PI	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AP			fields a	are not applicable	Rec. sell unit to cus	tomer?		Rx billing u	nit to pharma	icy:	
											-	
II. Generic Equivalent to What Bra							Vial		x	Each		
II. Generic Equivalent to What Bra	and?: Robinul®					(Write-in, e.g. 1 Vial)		J	x	Gram		
II. Generic Equivalent to What Bra	and?: Robinul®	PLY CHAIN SECURITY ACT (DSCSA) INFO	ORMATION					J	x			
II. Generic Equivalent to What Bra	and?: Robinul® DRUG SUPP		ORMATION	0370700000007)	I AND PACKING I		Gram Milliliter		
	and?: Robinul® DRUG SUPP ition of manufacturer?			037070000007)	I AND PACKING I		Gram Milliliter		
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption:	and?: Robinul® DRUG SUPP ition of manufacturer?	Yes G		037070000007) ITEN	Dimensi	NFORMATIO	Gram Milliliter N ts.)	Volume	# Pieces:
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	and?: Robinul® DRUG SUPP ition of manufacturer?	Yes C	GLN:			(Write-in, e.g. 1 Vial)) TEN Weight Lbs.		NFORMATIO	Gram Milliliter N ts.) Height	(Cube)	# Pieces:
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	and?: Robinul® DRUG SUPP ition of manufacturer?	Yes G No G	GLN: f Yes, was origin	037070000007) ITEN	Dimensi	NFORMATIO	Gram Milliliter N ts.)		# Pieces:
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	and?: Robinul® DRUG SUPP ition of manufacturer?	Yes G No If	GLN: f Yes, was origin direct from mfr?	nal product purchased		(Write-in, e.g. 1 Vial)	Weight Lbs.	Dimensi Depth	NFORMATIO	Gram Milliliter N ts.) Height	(Cube) 47.462912	
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	and?: Robinul® DRUG SUPP ition of manufacturer? s exclusive distributor? on/exemption for product?	Yes G No H No H No H	GLN: f Yes, was origin direct from mfr? f yes, attach doc			(Write-in, e.g. 1 Vial)	Weight Lbs.	Dimensi Depth	NFORMATIO	Gram Milliliter N ts.) Height	(Cube)	
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Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio	and?: Robinul® DRUG SUPP ition of manufacturer? s exclusive distributor? on/exemption for product? GT	Yes C No If No d No fil TIN AND HIBCC PRODUCT INFORMATIO	GLN: f Yes, was origin direct from mfr? f yes, attach doc N	nal product purchased cumentation from FDA.		(Write-in, e.g. 1 Vial)	Weight Lbs.	Dimensi Depth 6.46	NFORMATIO	Gram Milliliter N ts.) Height	(Cube) 47.462912 0 721.05	
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio	and?: Robinul® DRUG SUPP ition of manufacturer? s exclusive distributor? on/exemption for product?	Yes G No H No H No H	GLN: f Yes, was origin direct from mfr? f yes, attach doc N GTIN-	nal product purchased cumentation from FDA.	Unit of Use GTIN-14	(Write-in, e.g. 1 Vial)) ITEM Weight Lbs. 0.93 lb	Dimensi Depth 6.46	NFORMATIO ons (US msm Width 2.56	Gram Milliliter ts.) Height 2.87	(Cube) 47.462912 0	1
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Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio Saleable Unit of Measure Saleable Unit of Measure Case	and?: Robinul® DRUG SUPP ition of manufacturer? s exclusive distributor? on/exemption for product? GT Quantity_	Yes C No If No d No fil TIN AND HIBCC PRODUCT INFORMATIO	SLN: f Yes, was origin lifect from mfr? f yes, attach doc N GTIN- 00370	nal product purchased cumentation from FDA.	Unit of Use GTIN-14	(Write-in, e.g. 1 Vial) [Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet:) ITEM Weight Lbs. 0.93 lb	Dimensi Depth 6.46	NFORMATIO ons (US msm Width 2.56 6.9	Gram Milliliter Its.) Height 2.87 9.5	(Cube) 47.462912 0 721.05	1
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Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2020 For Designation	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 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 phar
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:



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

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?				