

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

Version 2021						Introduction 1	уре:	New Item		x Fir	nal Version			Date:	7/5/2	2023
			PRODUCT IN	FORMATION							SPECIAL HAN	IDLING AND STOR	AGE REQUI	REMENTS*		
Company Name: XIROMED LLC					Application: ANDA			a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 215825 Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)																
Medical Device Class, if applicab	ole:		·						1	•	ū					
DUNS:	080228637									Other Temp	erature Range	Requirement	None			
Proprietary Name (If Applicable) a	nd Established Na	me: Ep	hedrine Sulfate Injection	n, USP 50mg/mL					1	(write i	n)					
Selling Unit NDC:	70700-249-25		Unit of Us			UPC:	3707002	49253		Notes						
UDI			CVX Cod	de:		MVX Code:										
Description:	Ephedrine Sulfate	Injection, USP (1mL x 25 vials)						1	Is this produ	ct to be shippe	d to customers on ic	ce?		No	
										Is this produ	ct to be shippe	d to customers on d	ry ice?		No	
Active Ingredient(s):		Ephedrine Sulfa	ate													
									b. Contact for		excursion qu					
URL for Additional Product Inform Address:						Address 2:			-	Name:			VIPUL GANI			
City:	180 PARK AVE FLORHAM PARK				State:				Number: Group E-mail:			973-953-7867 VIPUL.GANDHI@XIROMED.COM;				
Key Contact:	DAVID HERNAND				Email:				Group E-mail:				VIFUL.GANDHI@XIKOMED.COM,			
Phone Number:	844-947-6633					Fax: 862-286-0932			c. Special regulations for product in any states?					No		
Product Therapeutic Classification									Special returns requirements for this product?							
r roudet merapeatic olassification	••									Opcolar rota	ino requiremen	to for this product:			140	
	ADDITIO	ONAL PRODUC	TINFORMATION			PRODUCT	DESCRIPT	TION INFORMATION	d. Store prod	uct (unit of s	ale) upright?				Yes	
The product is?			Is the Product	. Direct-Ship C	Only					-		ale) from light?			Yes	
a legend device?		No	Is the Product		,y		11	nL Vial	e. Shelf life:	1 Total pro	duct (dilit of 5	aic, iroin iigiit.			24	Months
if yes, enter class #		110	Orphan Drug St			Size:				Initial shelf	life at launch	(if different):			24	Months
a product kit?		No				Ctue w mth.	50	Omg/mL				,				
if yes, list NDCs of			FDA Approval S	Status		Strength:		-				ORDER INFORM	IATION			
component parts						Dosage Forn	n· IN	IJECTABLE								
reverse numbered?		No								Unit of Sale				NDC selling	unit?	
co-licensed?		No	Allergens Prese								ittle		1 Carton of 2			
latex-free? preservative-free?		Yes	Vial stopper is	not made with natural	I rubber	Product Sha	pe:				x/Carton		(Write-in, e.	g. 1 Box of 10	(Vials)	
correctional institution block?		Yes No		iatex							npule ass		Minimum or	der quantity	2	Yes
opioid?		No				Product Cole	or:				be		William Of	uer quaritity	•	163
Cannabinoid?		No	Country of Origin	India							al Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for		, ,			Product Imp	rint:				al Liquid Multi		If Yes, how	many of which	h package t	ype?
hospital scanning?			Is this product of				_			Via	al Powder Sql			Each	-	
If Unit Dose, indicate NDC here:			Trade Agreemer	nts Act (TAA)?	No						al Power Multi			Inner/Carton/	Pack	
]	Ot	her: Write In			Case		
			FOR GENERIC DE	RUG PRODUCTS												
						41	+15 A 41	d			DI	HARMACY ORDER	/ PILL LINIT			
					Au	thorized Generic		rized Generic, other elds are not applicable	_			TARMACT ORDER				
	AP	Akovaz					000001111	oldo dio not applicable	Rec. sell unit	to customer Carton of 25 \			Rx billing u	nit to pharma	cy:	
II. Generic Equivalent to What Bran	na?:	AKOVAZ							(Write-in, e.g.		riais			Each Gram		
		DRUG SU	PPLY CHAIN SECURIT	Y ACT (DSCSA) INFOR	RMATION				(vviite-iii, e.g.	i viai)				Milliliter		
				, ,												
Does supplier meet DSCSA definit	tion of manufactur	rer?	Yes		GLN:	0370700000007					ITE	M AND PACKING IN	NFORMATION	l		
Is product exempt from DSCSA?			No													
If yes, select exemption:					GCP:				1		Weight I be	Dimensi	ons (US msm	its.)	Volume	Saleable #
Other exemption - Write in:											Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			riginal product			Item/Each:		0.423	3.543307087	3.5433071	1.7716535	22.243155	1
Is product sold by manufacturer's			No No			rect from mfr?	_									
Has FDA granted waiver/exception If yes, attach documentation from		oduct?	INU		Provide sour	ce manufacturer fo	r repacka	ged product	Box/Carton/B	sundle/					0	
ir yes, attach documentation from	II FDA.								Case:							
			GTIN AND HIBCC PRO	DUCT INFORMATION					l Case.		22.48	15.35433071	11.614173	8.6614173	1544.572	48
									Pallet:							
Saleable Unit of Measure	S	aleable Quantity	HIBCC			N-14	1	Unit of Use GTIN-14							0	
x Item/Each		1			003	70700249253										
Box/Carton/Bundle/Inner Pack										COST I	IFORMATION		١	WHOLESALE	R USE ONL	Y:
x Case		48			103	70700249250			II				L			
Pallet	7						_		Regular	(1414 O) (A)		****	Vendor #:			
	-						-		Invoice Cost	(VVAC) (\$)		\$194.75	Whsl. Code Fineline Code			
	-								As of date:				i menne co			
	1												1			
							_		П							
			Attach copy of SAF	ETY DATA SHEET (SD	OS) or non haza	rd letter, PACKAGE	INSERT,	LABEL AND PHOTO OF I	PRODUCT PACKA	AGING and B	ARCODE.					
*Please provide any additional info	ormation on nago	2	* *	*				ed Dron Shin Only		Signature:						



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

M	ATERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply):							
a. Cytotoxic?	SDS Hazard Classification						
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 reproductive toxicant?	Inorganic	Oxidizer					
Does the product label bear a CA Prop 65 warning?	No	Steroid/Androgen	Contact Hazard				
c. Contact Hazard?	No	Does the product have an Aerosol class? If yes,	No				
d. Does this product require special clean-up instructions?	Yes	identify NFPA Storage Level:					
(If yes, attach SDS with special instructions.)		NFPA Storage Level:					
e. Does the product contain DEHP?	No						
Is this product regulated for shipment by DOT?	No	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 c. DOT Hazard Class	Hazardous Waste Identification						
d. Packing Group	- The Land Color of The Color o						
e. Inhalation Hazard?	No	EPA Hazardous Waste Code:	Waste Characteristics				
Is this product regulated for shipment by IATA?	No	-					
(if yes, answer a-e below and provide SDS)		REMS o	r REGISTRY RESTRICTIONS				
a. UN/Identification Number							
b. Proper Shipping Name		Is there a REMS on this product?	No				
c. DOT Hazard Class d. Packing Group		If Yes, is it managed with a pharmacy registry? Website URL:					
e. Inhalation Hazard?	No	Website ORL.					
Is the product restricted for air shipment? If so, indicate restriction:	No	Med Guide Required					
Passenger	140	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?		Supplier Manages REMS registry exclusively:					
Is this product shipped utilizing an authorized DOT exception or Special Permit? No (if yes, identify method below)		Wholesale distributor support: 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 Column 7 of 49 CFR 172.101);							
SP#		Registry:					
ADD'L STORAGE INFORMATION		Registry Program Contact Name: Comments		Phone:			
		Comments					
Is the Product Controlled Substance? No Controlled Substance Code		R	ETURN INSTRUCTIONS				
Controlled by State(s)? No Listed Chemical (List I or II)	Yes						
ARCOS Reportable? No If yes, indicate which: Ephedrine		Contact tel. # if product received damaged:					
Schedule No. Is it a scheduled listed chemical product?:	No	Is product returnable for credit:					
CLASS OF TRADE RESTRICTION:		URL/Link to returns policy:	-				
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices							
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:							
	MISCELLANEC	DUS NOTES and/or Image of Product Barcode:					
		JJ					



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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?					