

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

						Introduction Type	New Item		x Final Version			Date:	7/5/2	
			PRODUCT INFORMA	TION					SPECIAL HA	NDLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	XIROMED LLC					Application:	ANDA	a Temperatu	re - Indicate the USP tem	perature range for th	is product			
Application Number for NDA/AN		/A/510(k)(med devic	e):	2158	25			a. romporata	Temperature Range	Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applical									,					
DUNS:	080228637								Other Temperature Range	Requirement	None			
Proprietary Name (If Applicable) a	and Established Na	me: Ephedr	ine Sulfate Injection, USP	50mg/mL				1	(write in)	•				
Selling Unit NDC:	70700-249-23		Unit of Use NDC:				700249239		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Ephedrine Sulfate	Injection, USP (1mL	( 10 vials)					1	Is this product to be shipp	ed to customers on ic	e?		No	
	'	, , , , ,	,						Is this product to be shipp				No	
Active Ingredient(s):		Ephedrine Sulfate									-			
								b. Contact fo	r temperature excursion q	uestions:				
URL for Additional Product Inform		www.xiromed.co	<u>m</u>						Name:		VIPUL GANI			
Address:	180 PARK AVE					Address 2: #10			Number:		973-953-786			
City:	FLORHAM PARK				State:		o: 07932		Group E-mail:		VIPUL.GANI	HI@XIROM	ED.COM;	
Key Contact:	DAVID HERNANI	DEZ			Email: Fax:	DAVID.HERNANDE	Z@XIROMED.COM						NI.	ı
Phone Number:	844-947-6633				rax:	862-286-0932		c. Special reg	gulations for product in an				No	
Product Therapeutic Classificatio	on:								Special returns requireme	nts for this product?			No	
	ADDITI	ONAL PROPUST IN	OPMATION			PROPUST PEO	DIDTION INFORMATION							
	ADDIII	ONAL PRODUCT INF	ORMATION			PRODUCT DES	CRIPTION INFORMATION	d. Store prod	luct (unit of sale) upright?				Yes	
The product is?			Is the Product	Direct-Ship Onl	ly				Protect product (unit of	sale) from light?			Yes	
a legend device?		No	Is the Product	Neither		Size:	1mL Vial	e. Shelf life:					24	Months
if yes, enter class #		Te e	Orphan Drug Status						Initial shelf life at launch	(if different):			24	Months
a product kit?		No	EDA 4			Strength:	50mg/mL			ORDER INFORM	ATION			
if yes, list NDCs of component parts			FDA Approval Status				Injectable			ORDER INFORM	ATION			
reverse numbered?		No				Dosage Form:	Injectable		Unit of Sale		What is the	NDC salling	unit?	
co-licensed?		No	Allergens Present						Bottle		1 Carton of 1			
latex-free?		Yes	Vial stopper is not ma	ade with natural r	ubber				X Box/Carton		(Write-in, e.		) Vials)	
preservative-free?		Yes		atex		Product Shape:			Ampule				,	
correctional institution block?		No				Product Color:			Glass		Minimum or	der quantity	?	Yes
opioid?		No				Product Color:			Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint:			Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for					i roddot imprint.			Vial Liquid Multi		If Yes, how		ch package t	type?
hospital scanning?			Is this product covered in						Vial Powder Sql			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (	TAA)?   N	No				Vial Power Multi		1	Inner/Carton	/Pack	
				· · ·										
									Other: Write In			Case		
			FOR GENERIC DRUG PR											
			FOR GENERIC DRUG PR						Other: Write In					
			FOR GENERIC DRUG PR				Authorized Generic, other		Other: Write In	HARMACY ORDER	/ BILL UNIT	Case		
I. Orange Book Rating:	AP		FOR GENERIC DRUG PR				Authorized Generic, other tion fields are not applicable		Other: Write In	HARMACY ORDER	/ BILL UNIT Rx billing u	Case		
I. Orange Book Rating: II. Generic Equivalent to What Bra		Akovaz	FOR GENERIC DRUG PR					1 (	Other: Write In  P  It to customer?  Carton of 10 Vials	HARMACY ORDER	/ BILL UNIT	Case  iit to pharma Each		
				RODUCTS	Au				Other: Write In  P  It to customer?  Carton of 10 Vials	HARMACY ORDER	/ BILL UNIT Rx billing u	case  it to pharma Each Gram		
			FOR GENERIC DRUG PR	RODUCTS	Au			1 (	Other: Write In  P  It to customer?  Carton of 10 Vials	HARMACY ORDER	/ BILL UNIT Rx billing u	Case  iit to pharma Each		
II. Generic Equivalent to What Bra	and?:	DRUG SUPPL	CHAIN SECURITY ACT	RODUCTS  (DSCSA) INFORM	Au	sec		1 (	Other: Write In  P t to customer? Carton of 10 Vials . 1 Vial)		/ BILL UNIT Rx billing u	case  iit to pharma Each Gram Milliliter		
II. Generic Equivalent to What Bra	and?:	DRUG SUPPL	/ CHAIN SECURITY ACT Yes	RODUCTS  (DSCSA) INFORM	Au			1 (	Other: Write In  P t to customer? Carton of 10 Vials . 1 Vial)	HARMACY ORDER	/ BILL UNIT Rx billing u	case  iit to pharma Each Gram Milliliter		
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II. Generic Equivalent to What Bra  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	nd?: ition of manufactur s exclusive distribu	DRUG SUPPL	/ CHAIN SECURITY ACT  Yes  No	(DSCSA) INFORM	Au  MATION  GLN:  GCP:  f yes, was or ourchased di	0370700000007  Iginal product rect from mfr?	tion fields are not applicable	(Write-in, e.g	Other: Write In  P  It to customer? Carton of 10 Vials . 1 Vial)  Weight Lbs.  0.172	M AND PACKING IN Dimension	/ BILL UNIT  Rx billing us x  IFORMATION  Ons (US msm  Width	Case  iit to pharma Each Gram Milliliter  ts.) Height	Volume (Cube) 8.6501157	Pieces
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### **Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)**

### 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?	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			
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	Ната	rdous Waste Identification				
d. Packing Group		Hazardous Waste Identification				
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				



# **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?