

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

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			PRODUCT INFORMATION					SPECIAL HAN	DLING AND STOR	RAGE REQUI	REMENTS*		
	Company Name:	Xiromed LLC			Application:	ANDA	a. Temperatur	re – Indicate the USP temp	erature range for t	his product.			
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*Please provide any additional information on page 2. See new p. 3 for Designated Drop Ship Only. Signature:													
			Attach copy of SAFETY DATA SHE	EET (SDS) or non haz	ard letter, PACKAGE INSE	RT, LABEL AND PHOTO OF	PRODUCT PACK	AGING and BARCODE.					

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

Version 2020 For Designated Drop Ship Only Products, Please Use Page 3						
MATERIAL	HAZARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply): a. Cytotoxic? Yes b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? C. Contact Hazard? Yes	Organic x Corrosive Inorganic Oxidizer Steroid/Androgen x					
d. Does this product require special clean-up instructions? Yes (If yes, attach SDS with special instructions.) . e. Does the product contain DEHP? No Is this product regulated for shipment by DOT? No	Is the product a NIOSH hazardous drug? Yes If yes, indicate which: Group 1 items (antineoplastic)					
(if yes, answer a-e below and provide SDS)						
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics					
Is this product regulated for shipment by IATA? No	REMS or REGISTRY RESTRICTIONS					
is in product regulated to simplicit by IATA? 100 (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name	Is there a REMS on this product? No If Yes, is it managed with a pharmacy registry? Website URL:					
e. Inhalation Hazard?	Med Guide Required No					
Is the product restricted for air shipment? If so, indicate restriction:	Limited Distribution Requirement No Comments / Details: (For example, iPledge program?)					
Cargo Passenger & Cargo						
Is this a reportable quantity? Yes RQ Threshold: <u>Askan</u> Hydrogen Chloride - 2270kg Is this a marine pollutant? <u>No</u> Is this product shipped utilizing an authorized DOT exception or Special Permit? <u>No</u> (if yes, identify method below) Limited Quantity Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4) Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	REMS: Phone: REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: Phone: Wholesale distributor support: Provider Name: Site Enrollment Number assigned DEA #: by Supplier: NPI #: Comments					
SP#	Registry:					
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone: Comments					
Is the Product						
Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS					
Controlled by State(s)? No Listed Chemical (List I or II) No						
ARCOS Reportable? No If yes, indicate which:	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 Yes						
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 to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?					
Comments:						
MISCELLA	NEOUS 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 - if	not a designated drop ship, do not complete.				
Order Metho	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 Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #:	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: Hours Days Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:				
Expedited Freight C	Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing				
Expedited freight fees billed with each of Drop Ship service fee billed with each of Drop Ship miscellaneous fees billed: Comments:		Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday				
(Class of Trade Restriction:	PO Receipt Cut off time:				
No restriction: Select YES if sold to retain Restricted to retail pharmacy only: Restricted to hospital, clinics, and physic Restricted from US territories? (explain in Comments:		Saturday Overnight receipt available: PO Receipt Cut off time: PO Receipt Cut off time: Phone: Order receipt method: Phone: Fax: EDI: Overnight Fees apply: Image: Comparison of the state of th				
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?				