

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

				Introduction Type:	Post Launch Change		Final Version			Date:	7/10/	2024
		PRODUCT INFORMA	TION				SPECIAL HAN	IDLING AND STOR	RAGE REQUIR	REMENTS*		
Company Name:	Xiromed LLC Application: ANDA						a. Temperature – Indicate the USP temperature range for this product. Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)					
		d device):	212995			•	=		– between 20	and 25 C (68	- //· F)	
DUNS:	080228637						Temperature Range	Requirement				
Proprietary Name (If Applicable) a		Deferasirox Tablets, 90mg		1			write in)					
Selling Unit NDC: UDI	70700-269-30	Unit of Use NDC: CVX Code:		UPC: 37070 MVX Code:	0269305	Notes						
Description:	Deferasirox Tablets, 90mg - 30c			MVX Code.		Is this	product to be shippe	d to customers on i	ce?		No	
Active Ingredient(s):	Deferasirox					Is this	product to be shippe	d to customers on c	dry ice?		No	
						b. Contact for tempe		iestions:				
URL for Additional Product Inform						Name:			Xiromed Qua			
Address:	180 Park Ave		State	Address 2: Suite		Numb			844-947-663			
City:	Florham Park Xiromed Regulatory		Email			Group	E-mail:		US-Quality	-xiromea@	xiromed.co	<u>om</u>
Key Contact: Phone Number:	844-947-6633		Fax:	dor egulator (- mil or	ied.com	c. Special regulations	s for product in any	etatos?			No	
Product Therapeutic Classificatio		og Agent	- Luni	002 200 0002			l returns requiremen				No	
1 Todact Therapeatic Glassificatio	ii.	grigent				Оресіа	i returns requiremen	is for this product:			110	
	ADDITIONAL PRODUC	CT INFORMATION		PRODUCT DESC	RIPTION INFORMATION	d. Store product (uni	t of sale) upright?				Yes	
The product is?		Is the Product	Direct-Ship Only			11		ala\ fuama limbt?			Yes	
a legend device?	No	Is the Product	Neither		30 Count Bottle	e. Shelf life:	t product (unit of s	ale) from light?			24	Months
if yes, enter class #	NO	Orphan Drug Status	rveitriei	Size:	30 Count Bottle		shelf life at launch	(if different):			24	Months
a product kit?	No	Orphan Brug Glatus			90mg		onen me at laamen	(ii diliciciit).				Months
if yes, list NDCs of		FDA Approval Status		Strength:				ORDER INFORM	MATION			
component parts				Dosage Form:	Tablets							
reverse numbered?	No			Dosage i oiiii.		Unit of			What is the	NDC selling	unit?	
co-licensed?	No	Allergens Present				x			1 Bottle			
latex-free?	No	Not made with nat	ural rubber latex.	Product Shape:	Film-coated, oval biconvex		Box/Carton		(Write-in, e.	g. 1 Box of 1) Vials)	
preservative-free?	Yes			•	Dive		Ampule				•	V
correctional institution block? opioid?	Yes No			Product Color:	Blue		Glass Tube		Minimum or	der quantity		Yes
Cannabinoid?	No No	Country of Origin	India		Debossed "90" on one		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u		Country of Origin	iliula	Product Imprint:	side		Vial Liquid Sgi Vial Liquid Multi		If Yes how	many of whi	ch package t	vne?
scanning?	The dose for Hospital	Is this product covered up	nder the		side		Vial Powder Sql			Each	cii package i	ype:
If Unit Dose, indicate NDC here:		Trade Agreements Act (T					Vial Power Multi			Inner/Carton	/Pack	
,			<i>'</i>				Other: Write In			Case		
		FOR GENERIC DRUG PR	ODUCTS	•		<u></u>				.!!		
			-						_			
				uthorized Conorio *If Aut	horized Generic, other section		PI	HARMACY ORDER				
I. Orange Book Rating:			A	authorized Generic *If Aut			• •	TARMACT URDER	R / BILL UNIT			
II. Generic Equivalent to What Bra	AB		^		are not applicable	Rec. sell unit to cust		TARMACT ORDER		nit to pharm	acy:	
			A			Rec. sell unit to cust	omer?	TARWACT ORDER	Rx billing u	nit to pharm Each	асу:	
	and?: Jadenu						omer?	ARMACT ORDER	Rx billing u	Each Gram	асу:	
	and?: Jadenu	SUPPLY CHAIN SECURITY ACT (1 Bo	omer?	ARMACT ORDER	Rx billing u	Each	acy:	
Dogo cumplior most DOCOA defici	Jadenu DRUG S	· · · · · · · · · · · · · · · · · · ·	(DSCSA) INFORMATION	fields a		1 Bo	omer? ttle]	Rx billing u	Each Gram Milliliter	acy:	
Does supplier meet DSCSA defini	Jadenu DRUG S	Yes				1 Bo	omer? ttle	M AND PACKING I	Rx billing u	Each Gram Milliliter	асу:	
Is product exempt from DSCSA?	Jadenu DRUG S	· · · · · · · · · · · · · · · · · · ·	(DSCSA) INFORMATION	fields a		1 Bo	omer? ttle	M AND PACKING I	Rx billing u	Each Gram Milliliter		
Is product exempt from DSCSA? If yes, select exemption:	Jadenu DRUG S	Yes	(DSCSA) INFORMATION	fields a		1 Bo	omer? ttle	M AND PACKING I	Rx billing un x NFORMATION ions (US msm	Each Gram Milliliter	Volume	#Pieces:
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	Jadenu DRUG S	Yes No	(DSCSA) INFORMATION GLN:	037070000007		(Write-in, e.g. 1 Vial)	omer? Ittle ITEI Weight Lbs.	M AND PACKING I Dimensi Depth	Rx billing un x NFORMATION ions (US msm Width	Each Gram Milliliter N Its.) Height	Volume (Cube)	
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	DRUG S ition of manufacturer?	Yes No No	(DSCSA) INFORMATION GLN:	fields :		1 Bo	omer? vittle	M AND PACKING I	Rx billing un x NFORMATION ions (US msm	Each Gram Milliliter	Volume	#Pieces:
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	DRUG S ition of manufacturer?	Yes No	GLN: If Yes, was or direct from m	fields : 0370700000007 riginal product purchased nfr?		(Write-in, e.g. 1 Vial)	omer? Ittle ITEI Weight Lbs.	M AND PACKING I Dimensi Depth	Rx billing un x NFORMATION ions (US msm Width	Each Gram Milliliter N Its.) Height	Volume (Cube) 9.4769015	
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	DRUG S ition of manufacturer?	Yes No No	GLN: If Yes, was or direct from m	fields :		(Write-in, e.g. 1 Vial)	omer? Ittle ITEI Weight Lbs.	M AND PACKING I Dimensi Depth	Rx billing un x NFORMATION ions (US msm Width	Each Gram Milliliter N Its.) Height	Volume (Cube)	
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	DRUG S ition of manufacturer?	Yes No No	GLN: If Yes, was ordirect from many if yes, attach	fields : 0370700000007 riginal product purchased nfr?		1 Bc (Write-in, e.g. 1 Vial)	weight Lbs.	Dimensi Depth 1.705	NFORMATION ions (US msm Width 1.705	Each Gram Milliliter N Ints.) Height 3.26	Volume (Cube) 9.4769015	1
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?: Jadenu DRUG S ition of manufacturer? s exclusive distributor? n/exemption for product?	No No No No On No On	(DSCSA) INFORMATION GLN: If Yes, was or direct from m If yes, attach	fields : 0370700000007 riginal product purchased fir? documentation from FDA.	are not applicable	(Write-in, e.g. 1 Vial) Item/Each: Box/Carton/Bundle/ Inner Pack: Case:	omer? Ittle ITEI Weight Lbs.	M AND PACKING I Dimensi Depth	Rx billing un x NFORMATION ions (US msm Width	Each Gram Milliliter N Its.) Height	Volume (Cube) 9.4769015	
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	DRUG S ition of manufacturer?	Yes No No No No No	GLN: If Yes, was ordirect from mile yes, attach	riginal product purchased nfr? documentation from FDA.		(Write-in, e.g. 1 Vial) Item/Each: Box/Carton/Bundle/ Inner Pack:	weight Lbs.	Dimensi Depth 1.705	NFORMATION ions (US msm Width 1.705	Each Gram Milliliter N Ints.) Height 3.26	Volume (Cube) 9.4769015	1
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	and?: Jadenu DRUG S ition of manufacturer? s exclusive distributor? n/exemption for product?	No No No No On No On	GLN: If Yes, was ordirect from mile yes, attach	fields : 0370700000007 riginal product purchased fir? documentation from FDA.	are not applicable	(Write-in, e.g. 1 Vial) Item/Each: Box/Carton/Bundle/ Inner Pack: Case:	weight Lbs.	Dimensi Depth 1.705	NFORMATION ions (US msm Width 1.705	Each Gram Milliliter N Ints.) Height 3.26	Volume (Cube) 9.4769015 0 147.97266	1
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 Item/Each Box/Carton/Bundle/Inner Pack	BRUG S ition of manufacturer? s exclusive distributor? In/exemption for product? Quantity Quantity	No No No No On No On	(DSCSA) INFORMATION GLN: If Yes, was or direct from m if yes, attach NFORMATION GT	fields : 0370700000007 riginal product purchased offr? documentation from FDA.	are not applicable	1 Bo (Write-in, e.g. 1 Vial) Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet:	Weight Lbs. 0.12 1.44	Dimensi Depth 1.705	NFORMATION ions (US msm Width 1.705	Each Gram Milliliter	Volume (Cube) 9.4769015 0 147.97266	1 12
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 Item/Each Box/Carton/Bundle/Inner Pack X Case	and?: Jadenu DRUG S ition of manufacturer? s exclusive distributor? n/exemption for product?	No No No No On No On	(DSCSA) INFORMATION GLN: If Yes, was or direct from m if yes, attach NFORMATION GT	riginal product purchased nfr? documentation from FDA.	are not applicable	1 Bo (Write-in, e.g. 1 Vial) Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet:	weight Lbs.	Dimensi Depth 1.705	NFORMATION ions (US msm Width 1.705	Each Gram Milliliter	Volume (Cube) 9.4769015 0 147.97266	1 12
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 Item/Each Box/Carton/Bundle/Inner Pack	BRUG S ition of manufacturer? s exclusive distributor? In/exemption for product? Quantity Quantity	No No No No On No On	(DSCSA) INFORMATION GLN: If Yes, was or direct from m if yes, attach NFORMATION GT	fields : 0370700000007 riginal product purchased offr? documentation from FDA.	are not applicable	Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet:	Weight Lbs. 0.12 1.44	Dimensi Depth 1.705	NFORMATION ions (US msm Width 1.705 5.75	Each Gram Milliliter	Volume (Cube) 9.4769015 0 147.97266	1 12
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 Item/Each Box/Carton/Bundle/Inner Pack X Case	BRUG S ition of manufacturer? s exclusive distributor? In/exemption for product? Quantity Quantity	No No No No On No On	(DSCSA) INFORMATION GLN: If Yes, was or direct from m if yes, attach NFORMATION GT	fields : 0370700000007 riginal product purchased offr? documentation from FDA.	are not applicable	Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet:	Weight Lbs. 0.12 1.44 DST INFORMATION	Dimensi Depth 1.705 7.625	Rx billing un x NFORMATION ions (US msm Width 1.705 5.75	Each Gram Milliliter N Height 3.26 3.375	Volume (Cube) 9.4769015 0 147.97266	1 12
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 Item/Each Box/Carton/Bundle/Inner Pack X Case	BRUG S ition of manufacturer? s exclusive distributor? In/exemption for product? Quantity Quantity	No No No No On No On	(DSCSA) INFORMATION GLN: If Yes, was or direct from m if yes, attach NFORMATION GT	fields : 0370700000007 riginal product purchased offr? documentation from FDA.	are not applicable	Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet:	Weight Lbs. 0.12 1.44 DST INFORMATION	Dimensi Depth 1.705 7.625	NFORMATION ions (US msm Width 1.705 5.75 Vendor #: Whsl. Code	Each Gram Milliliter N Atts.) Height 3.26 3.375	Volume (Cube) 9.4769015 0 147.97266	1 12
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 Item/Each Box/Carton/Bundle/Inner Pack X Case	BRUG S ition of manufacturer? s exclusive distributor? In/exemption for product? Quantity Quantity	No No No No On No On	(DSCSA) INFORMATION GLN: If Yes, was or direct from m if yes, attach NFORMATION GT	fields : 0370700000007 riginal product purchased offr? documentation from FDA.	are not applicable	Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet: Regular Cost Invoice Cost (WAC)	Weight Lbs. 0.12 1.44 DST INFORMATION	Dimensi Depth 1.705 7.625	Rx billing un x NFORMATION ions (US msm Width 1.705 5.75	Each Gram Milliliter N Atts.) Height 3.26 3.375	Volume (Cube) 9.4769015 0 147.97266	1 12
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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 Item/Each Box/Carton/Bundle/Inner Pack X Case	BRUG S ition of manufacturer? s exclusive distributor? In/exemption for product? Quantity Quantity	No No No No No HIBCC	If Yes, was or direct from m If yes, attach	fields : 0370700000007 riginal product purchased of fr? documentation from FDA. IIN-14 370700269305 370700269302	are not applicable	Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet: CC Regular Cost Invoice Cost (WAC) (As of date:	Weight Lbs. 0.12 1.44 SST INFORMATION \$)	Dimensi Depth 1.705 7.625	NFORMATION ions (US msm Width 1.705 5.75 Vendor #: Whsl. Code	Each Gram Milliliter N Atts.) Height 3.26 3.375	Volume (Cube) 9.4769015 0 147.97266	1 12



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

Version 2020

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HA	ZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply): a. Cytotoxic? No	SDS Hazard Classification						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	ODO Hazard Glassification						
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?	Steroid/Androgen Contact Hazard						
c. Contact Hazard?	Aerosol Class; Identify NFPA Storage Level:						
d. Does this product require special clean-up instructions?							
(If yes, attach SDS with special instructions.)	Is the product a NIOSH hazardous drug? No						
e. Does the product contain DEHP?	If yes, indicate which:						
Is this product regulated for shipment by DOT?							
(if yes, answer a-e below and provide SDS)							
a. UN/Identification Number	Hazardous Waste Identification						
b. Proper Shipping Name							
c. DOT Hazard Class	EPA Hazardous Waste Code: Waste Characteristics						
d. Packing Group							
e. Inhalation Hazard?							
Is this product regulated for shipment by IATA?	REMS or REGISTRY RESTRICTIONS						
(if yes, answer a-e below and provide SDS)	Is there a REMS on this product? No						
a. UN/Identification Number	If Yes, is it managed with a pharmacy registry?						
b. Proper Shipping Name	Website URL:						
c. DOT Hazard Class							
d. Packing Group							
e. Inhalation Hazard?	Med Guide Required No						
Is the product restricted for air shipment? If so, indicate restriction:	Limited Distribution Requirement No						
Passenger	Comments / Details: (For example, iPledge program?)						
Cargo							
Passenger & Cargo							
Is this a reportable quantity? No	REMS:						
RQ Threshold:	REMS Program Manager Name: Phone:						
Is this a marine pollutant? No	Supplier Manages REMS registry exclusively:						
Is this product shipped utilizing an authorized DOT exception or Special Permit?	Wholesale distributor support:						
No (if yes, identify method below)	Provider Name: DEA #:						
Limited Quantity	Site Enrollment Number assigned PCPDP#:						
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:						
	Registry Program Contact Name: Phone:						
ADD'L STORAGE INFORMATION	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	ls product returnable for credit:						
CLASS OF TRADE RESTRICTION:	URL/Link to returns policy:						
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:	1						
MISCELLANE	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 - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Pr	oduct	Standard Order Receipt and Processing
Purchase orders may be accepted by:		Purchase order daily receipt cut off time by supplier
a. EDI		Cut off time:
b. Autofax Fax Number:		
c. Fax Number:		Shipping lead time of PO: Hours Days
d. Phone only Phone No.:		
e. Supplier Web Site only Site Address: Minimum Order Quantity:		Ships same day for next day receipt: Ships for second day receipt:
Supplier's Customer Service Number:		Ships regular ground for 3-10 days receipt:
Contracted 3PL company / contact #: Name:		Chips regular ground for 5-10 days receipt.
Phone:		
Expedited Freight Charges or Other Designated Dr	op Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:		Overnight receipt available:
Drop Ship service fee billed with each order:		PO Receipt cut off time:
Drop Ship miscellaneous fees billed:		Days of week overnight is available: Monday
Comments:		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	nhysician offices	Saturday Overnight receipt available:
Restricted to retail pharmacy only:	priysician onices	PO Receipt Cut off time:
Restricted to hospital, clinics, and physician offices only:		Phone #
Restricted from US territories? (explain in comments)		Order receipt method: Fax: Fax#:
Comments:		EDI:
		Overnight Fees apply:
		Other fees apply:
Other Data Information Required to Proces	s PO:	Return Instructions
Patient Procedure Date:		Contact # if product is received damaged:
Physician Name:		Is product returnable for credit:
Physician/Clinic Phone #		URL/Link to returns policy:
Physician State License #		Special regulations or returns requirements for this product in certain states?
Physician/Clinic DEA #: Physician/Clinic Specialty:		If so, which states? Other requirements? Comments?
		il so, which states? Other requirements? Comments?
Miscellaneous Notes:		
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure?
		Is product order for restocking purposes?