

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

Version 2020						Introduction Type:	Post Launch Change	]	Final Version			Date:	10/8/	2021
			PRODUCT INFORMA	ATION					SPECIAL HA	NDLING AND STO	RAGE REQUI	REMENTS*		
Company Name:	Xiromed LLC Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/AN	NDA/BLA (drug); PMA/5	10(k)(med device	e):	210	0123			11	Temperature Range	Controlled Room		and 25 C (68°	– 77° F)	
DUNS:	080228637				1				Other Temperature Range	Requirement				
Proprietary Name (If Applicable)		FLUOR	OURACIL						(write in)	•				
Selling Unit NDC:	70700-187-23		Unit of Use NDC:				0187234		Notes					
UDI			CVX Code:			MVX Code:		]						
Description:	Fluorouracil Injection,	USP 1g/20mL 10	0x20mL Single-Dose Vials						Is this product to be shippe				No	
Active Ingredient(s):	FL	UOROURACIL						1	Is this product to be shippe	d to customers on d	ry ice?		No	
								b. Contact for	temperature excursion qu	uestions:				
URL for Additional Product Inform Address:	mation: 180 Park Ave					Address 2: Suite			Name:		Steven Yeur			
City:	Florham Park				State:		07932	4	Number: Group E-mail:		844-947-663	ng@xirome	nd com	
Key Contact:	David Hernandez				Email:	david.hernandez@x		1	Group E-mail.		steven.yeu	ng@xironie	u.com	
Phone Number:	844-947-6633				Fax:	862-286-0932	iromed.com	c. Special reg	ulations for product in any	states?			No	
Product Therapeutic Classification								]	Special returns requiremen				No	
					4				.,					
	ADDITIONA	L PRODUCT INFO	ORMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store produ	uct (unit of sale) upright?					
The product is?			Is the Product	Direct-Ship O	nly				Protect product (unit of s	ale) from light?			Yes	
a legend device?	No	,	Is the Product	Neither	-	Size:	10 x 20mL Single-dose	e. Shelf life:		-			24	Months
if yes, enter class #			Orphan Drug Status			Size.	vials		Initial shelf life at launch	(if different):				Months
a product kit?	No	<u> </u>				Strength:	1GM/20ML (50MG/ML)							
if yes, list NDCs of			FDA Approval Status			<b>.</b>	IN JEOTADI E			ORDER INFORI	MATION			
component parts reverse numbered?	Na					Dosage Form:	INJECTABLE		Unit of Sale		What is the	IDC calling	unit?	
co-licensed?	No No		Allergens Present						Bottle		1 Box contai		unit:	
latex-free?	Ye		Container closure is n	not made with n	atural				x Box/Carton		(Write-in, e.		(Vials)	
preservative-free?	Ye		rubber			Product Shape:			Ampule		(	,	,	
correctional institution block?						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	unit dose for					i i oddot iii piiitti			Vial Liquid Multi				ch package ty	ype?
hospital scanning?	_		Is this product covered un Trade Agreements Act (		NI.				Vial Powder Sql		12	Each	/DI-	
If Unit Dose, indicate NDC here:			Trade Agreements Act (	TAA)?	No				Vial Power Multi Other: Write In			Inner/Carton Case	Раск	
			FOR GENERIC DRUG PF	RODUCTS				<u> </u>	Canon vinto in			ouoo		
			TON SENEMIS BROST								_			
					Auth		horized Generic, other section		P	HARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AP					fields	are not applicable	Rec. sell unit	to customer?		Rx billing ur	it to pharma	cy:	
II. Generic Equivalent to What Bra	and?:							1			х	Each	-	
		•						1 Box	containing 10 Vials			_		
								(Write-in, e.g.				Gram		
		DRUG SUPPLY	Y CHAIN SECURITY ACT	(DSCSA) INFOR	RMATION					_		Gram Milliliter		
Does supplier meet DSCSA defin	ition of manufacturer?			· /		037070000007			1 Vial)	M AND PACKING I	NEORMATIO	Milliliter		
Does supplier meet DSCSA defin Is product exempt from DSCSA?			Yes No	(DSCSA) INFOR		0370700000007			1 Vial)	M AND PACKING I	NFORMATIO	Milliliter		
Is product exempt from DSCSA?			Yes	· /		037070000007			1 Vial)			Milliliter	Volume	
			Yes	· /		037070000007			1 Vial)		NFORMATION Sions (US msm	Milliliter	Volume (Cube)	# Pieces:
Is product exempt from DSCSA?  If yes, select exemption:  Other exemption - Write in: Is product repackaged?	, 	_	Yes No	GLI	.N: /es, was origii	nal product purchased			1 Vial)  TE  Weight Lbs.	Dimens Depth	ions (US msm Width	Milliliter  ts.)  Height	(Cube)	
Is product exempt from DSCSA?  If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer	's exclusive distributor?	?	Yes No No	GLI	.N: /es, was origin ect from mfr?	nal product purchased		(Write-in, e.g.	1 Vial)  Weight Lbs.  1.168	Dimens	ions (US msm	Milliliter  ts.)		# Pieces:
Is product exempt from DSCSA?  If yes, select exemption:  Other exemption - Write in: Is product repackaged?	's exclusive distributor?	?	Yes No	GLI	.N: /es, was origin ect from mfr?	nal product purchased		(Write-in, e.g.	1 Vial)  Weight Lbs.  1.168	Dimens Depth	ions (US msm Width	Milliliter  ts.)  Height	(Cube)	
Is product exempt from DSCSA?  If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer	's exclusive distributor?	? cct?	Yes No No No No	GLI  If Y  dire	.N: /es, was origin ect from mfr?	nal product purchased		(Write-in, e.g.  Item/Each:  Box/Carton/B Inner Pack:	1 Vial)  Weight Lbs.  1.168  undle/	Dimensi Depth 6.457	ons (US msm Width 2.559	Milliliter  ts.)  Height  2.874	(Cube) 47.488433 0	1
Is product exempt from DSCSA?  If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer	's exclusive distributor?	? cct?	Yes No No	GLI  If Y  dire	.N: /es, was origin ect from mfr?	nal product purchased		(Write-in, e.g.	1 Vial)  Weight Lbs.  1.168	Dimens Depth	ions (US msm Width	Milliliter  ts.)  Height	(Cube) 47.488433	
Is product exempt from DSCSA?  If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer	's exclusive distributor? on/exemption for produce	? cct?	Yes No No No No	GLI  If Y  dire	.N: /es, was origin ect from mfr?	nal product purchased cumentation from FDA.	Unit of Use GTIN-14	(Write-in, e.g.  Item/Each:  Box/Carton/B Inner Pack:	1 Vial)  Weight Lbs.  1.168  undle/	Dimensi Depth 6.457	ons (US msm Width 2.559	Milliliter  ts.)  Height  2.874	(Cube) 47.488433 0 717.7022	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/exception	's exclusive distributor? on/exemption for produce	? cct?	Yes No No No No No No No No	GLI  If Y  dire	N:  /es, was origin ect from mfr? /es, attach doo	nal product purchased cumentation from FDA.	Unit of Use GTIN-14	Item/Each:   Box/Carton/B   Inner Pack:   Case:	1 Vial)  Weight Lbs.  1.168  undle/	Dimensi Depth 6.457	ons (US msm Width 2.559	Milliliter  ts.)  Height  2.874	(Cube) 47.488433 0	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/exception  Saleable Unit of Measure  X Item/Each Bow/Carton/Bundle/Inner Pack	's exclusive distributor? on/exemption for produce	GTIN	Yes No No No No No No No No	GLI  If Y  dire	/es, was origing ect from mfr? res, attach door GTIN-	nal product purchased cumentation from FDA.	Unit of Use GTIN-14	Item/Each:   Box/Carton/B   Inner Pack:   Case:	1 Vial)  Weight Lbs.  1.168  undle/	Dimensi Depth 6.457	ons (US msm Width 2.559 6.89	Milliliter  ts.)  Height  2.874	(Cube) 47.488433 0 717.7022 0	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/exception  Saleable Unit of Measure  x Item/Each Bow/Carton/Bundle/Inner Pack Case	's exclusive distributor? on/exemption for produce	? cct?	Yes No No No No No No No No	GLI  If Y  dire	/es, was origing ect from mfr? res, attach door GTIN-	nal product purchased cumentation from FDA.	Unit of Use GTIN-14	Item/Each:   Box/Carton/B   Inner Pack:   Case:	1 Vial)  Weight Lbs.  1.168  undle/	Dimensi Depth 6.457	ons (US msm Width 2.559 6.89	Milliliter  ts.)  Height  2.874	(Cube) 47.488433 0 717.7022	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/exception  Saleable Unit of Measure  X	's exclusive distributor? on/exemption for produce	GTIN	Yes No No No No No No No No	GLI  If Y  dire	/es, was origing ect from mfr? res, attach door GTIN-	nal product purchased cumentation from FDA.	Unit of Use GTIN-14	ltem/Each: Box/Carton/B Inner Pack: Case: Pallet:	1 Vial)  Weight Lbs.  1.168  undle/	Dimensi Depth 6.457	ons (US msm Width 2.559 6.89	Milliliter  ts.)  Height  2.874	(Cube) 47.488433 0 717.7022 0	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/exception  Saleable Unit of Measure  x Item/Each Bow/Carton/Bundle/Inner Pack Case	's exclusive distributor? on/exemption for produce	GTIN	Yes No No No No No No No No	GLI  If Y  dire	/es, was origing ect from mfr? res, attach door GTIN-	nal product purchased cumentation from FDA.	Unit of Use GTIN-14	(Write-in, e.g.  Item/Each: Box/Carton/B Inner Pack: Case: Pallet:	1 Vial)  Weight Lbs.  1.168  undle/  15.653  COST INFORMATION	Dimensi Depth 6.457 11.024	ons (US msm Width 2.559 6.89	Milliliter  ts.) Height 2.874  9.449	(Cube) 47.488433 0 717.7022 0	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/exception  Saleable Unit of Measure  x Item/Each Bow/Carton/Bundle/Inner Pack Case	's exclusive distributor? on/exemption for produce	GTIN	Yes No No No No No No No No	GLI  If Y  dire	/es, was origing ect from mfr? res, attach door GTIN-	nal product purchased cumentation from FDA.	Unit of Use GTIN-14	ltem/Each: Box/Carton/B Inner Pack: Case: Pallet:	1 Vial)  Weight Lbs.  1.168  undle/  15.653  COST INFORMATION	Dimensi Depth 6.457	ons (US msm Width 2.559 6.89	Milliliter  ts.) Height 2.874  9.449	(Cube) 47.488433 0 717.7022 0	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/exception  Saleable Unit of Measure  x Item/Each Bow/Carton/Bundle/Inner Pack Case	's exclusive distributor? on/exemption for produce	GTIN	Yes No No No No No No No No	GLI  If Y  dire	/es, was origing ect from mfr? res, attach door GTIN-	nal product purchased cumentation from FDA.	Unit of Use GTIN-14	(Write-in, e.g.  Item/Each: Box/Carton/B Inner Pack: Case: Pallet:	1 Vial)  Weight Lbs.  1.168  undle/  15.653  COST INFORMATION	Dimensi Depth 6.457 11.024	ons (US msm Width 2.559 6.89	Milliliter  ts.) Height 2.874  9.449	(Cube) 47.488433 0 717.7022 0	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/exception  Saleable Unit of Measure  x Item/Each Bow/Carton/Bundle/Inner Pack Case	's exclusive distributor? on/exemption for produce	GTIN	Yes No No No No No No No No	GLI  If Y  dire	/es, was origing ect from mfr? res, attach door GTIN-	nal product purchased cumentation from FDA.	Unit of Use GTIN-14	ltem/Each: Box/Carton/B Inner Pack: Case: Pallet: Regular Cost Invoice Cost (	1 Vial)  Weight Lbs.  1.168  undle/  15.653  COST INFORMATION	Dimensi Depth 6.457 11.024	ons (US msm Width 2.559 6.89	Milliliter  ts.) Height 2.874  9.449	(Cube) 47.488433 0 717.7022 0	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/exception  Saleable Unit of Measure  x Item/Each Bow/Carton/Bundle/Inner Pack Case	's exclusive distributor? on/exemption for produce	GTIN  GTIN  1  12	Yes No	GLI  If Y dire  If y or	res, was origin ect from mfr? res, attach doc	nal product purchased cumentation from FDA.	Unit of Use GTIN-14  ERT, LABEL AND PHOTO OF	Item/Each:   Box/Carton/B   Inner Pack:   Case:   Pallet:   Regular Cost   Invoice Cost (   As of date:	Weight Lbs.  1.168  undle/  15.653  COST INFORMATION  (WAC) (\$)	Dimensi Depth 6.457 11.024	ons (US msm Width 2.559 6.89	Milliliter  ts.) Height 2.874  9.449	(Cube) 47.488433 0 717.7022 0	1 12



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

Version 2020

For Designated Drop Ship Only Products, Please Use Page 3

	AL HAZARD CLASSIFICATION and TRANSPORTATION
· · ·	SDS Hazard Classification
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 Organic Corrosive Oxidizer Contact Hazard
c. Contact Hazard? d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP?  Is this product regulated for shipment by DOT?	No No Aerosol Class; Identify NFPA Storage Level:  Is the product a NIOSH hazardous drug?  If yes, indicate which:  Yes  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	Hazardous Waste Identification  EPA Hazardous Waste Code: Waste Characteristics
d. Packing Group e. Inhalation Hazard?	No DELICATION DE CARRIENTO NO
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class	No REMS or REGISTRY RESTRICTIONS  Is there a REMS on this product? No  If Yes, is it managed with a pharmacy registry?  Website URL:
d. Packing Group e. Inhalation Hazard?  Is the product restricted for air shipment? If so, indicate restriction:  Passenger Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)
Passenger & Cargo  Is this a reportable quantity? Yes RQ Threshold: 500  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)	REMS:  REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier:  PROVIDENTIAL PROPERS TO BE A #: PCPDP#: NPI #:
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments  Registry:
ADD'L STORAGE INFORMATION Is the Product	Registry Program Contact Name: Phone: Comments
Controlled Substance? Controlled by State(s)? ARCOS Reportable? Schedule No.  No Listed Chemical (List I or II) If yes, indicate which: Is it a scheduled listed chemical product?:  CLASS OF TRADE RESTRICTION:	No No No Understand the state of the state o
Restricted to retail pharmacy only:  Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)  Comments:	Special regulations or returns requirements for this product in certain states?  If so, which states? Other requirements? Comments?
	_LANEOUS 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	r Designated Drop Ship Product	Standard Order Receipt and Process	sing
Purchase orders may be accepted by:		Purchase order daily receipt cut off time by supplier	
a. EDI		Cut off time:	311
b. Autofax	Fax Number:		
c. Fax	Fax Number:	Shipping lead time of PO: Hours	Days
d. Phone only	Phone No.:		
e. Supplier Web Site only	Site Address:	Ships same day for next day receipt:	
Minimum Order Quantity: Supplier's Customer Service Number:		Ships for second day receipt: Ships regular ground for 3-10 days receipt:	
	lame:	Ships regular ground for 3-10 days receipt.	
	Phone:		
Expedited Freight Charge	es or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Pro	cessing
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:		Days of week overliight is available.	Tuesday
Gommonio.			Wednesday
			Thursday
			Friday
		Priority Overnight receipt available:	
Class	of Trade Restriction:	PO Receipt Cut off time:	
No restriction: Select YES if sold to retail phar		Saturday Overnight receipt available:	
Restricted to retail pharmacy only:	mady, neophale, climed and physician chiese	PO Receipt Cut off time:	
Restricted to hospital, clinics, and physician of	ffices only:	Order receipt method: Phone: Phone #:	
Restricted from US territories? (explain in com		Fax: Fax #:	
Comments:		EDI:	•
		Overnight Fees apply:	
		Other fees apply:	
Other Data Infor	mation Required to Process 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 # Physician/Clinic DEA #:		Special regulations or returns requirements for this product in certa	ain states?
Physician/Clinic Specialty:		If so, which states? Other requirements? Comments?	iii states:
_ · · · · · · · · · · · · · · · · · · ·	scellaneous Notes:	·	
		ADDITIONAL INFORMATION	
		Is product order for scheduled patient procedure?	
		Is product order for restocking purposes?	