

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

Version 2020			Introduction Type:	New Item		Final Version			Date:	7/10/	/2024	
PRODUCT INFORMATION						SPECIAL HANDLING AND STORAGE REQUIREMENTS*						
Company Name:	Xiromed LLC Application: ANDA				a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/AN	DA/BLA (drug); PMA/510(k)(med devie	ce): 212993	Ter	mperature Range	Controlled Room	- between 20	and 25 C (68	» – 77° F)				
DUNS:	080228637				Oth	ner Temperature Range I	Requirement					
Proprietary Name (If Applicable) a Selling Unit NDC:	nd Established Name: Irinotec: 70700-169-22	an Hydrochloride Unit of Use NDC:	UPC: 370700	460000	No	(write in)						
	70700-189-22	CVX Code:	MVX Code:	169223	INO	les						
Description:	Irinotecan Hydrochloride Injection USP				l ls t	his product to be shipped	to customers on in			No		
Decomption						his product to be shipped				No	-	
Active Ingredient(s):	Irinotecan Hydrochl											
URL for Additional Product Inform	b. Contact for temperature excursion questions: Name: Xiromed Quality											
Address:	180 Park Ave		Address 2: Suite 1	01		mber:		844-947-663				
City:	Florham Park			07932	Gr	oup E-mail:				axiromed.co	om	
Key Contact:	Xiromed Regulatory		nail: usregulatory@xirom	ed.com								
Phone Number: Product Therapeutic Classificatio	844-947-6633	Fa	ax: 862-286-0932			ions for product in any				No	-	
Flouter merapeutic classificatio					Sp	ecial returns requirement	s for this product?			No	-	
	ADDITIONAL PRODUCT INF	ORMATION	PRODUCT DESCR	IPTION INFORMATION	d. Store product (unit of sale) upright? Yes							
The product is?		Is the Product Direct-Ship Only			Pro	otect product (unit of sa	ale) from light?			Yes		
a legend device?	No	Is the Product Neither	Size:	2mL Vial	e. Shelf life:					24	Months	
if yes, enter class # a product kit?	No	Orphan Drug Status		40MG/2ML (20MG/ML)	Init	tial shelf life at launch (if different):				Months	
if yes, list NDCs of	NO	FDA Approval Status	Strength:	401VIG/21VIL (201VIG/IVIL)			ORDER INFORM	IATION				
component parts		· ·	Dosage Form:	Injectable								
reverse numbered?	No				Un	it of Sale Bottle		What is the		unit?		
co-licensed? latex-free?	No Yes	Allergens Present Not made with natural rubber latex. Free from				Bottle Box/Carton		1 Box of 10 V	/ials g. 1 Box of 1	0 Vials)		
preservative-free?	Yes	Gluten, Lactose, Sweeteners, Soy, and Gelatin	Product Shape:			Ampule		(11110 111, 0.	g. 1 Dox of 1	s vialo)		
correctional institution block?	Yes		Product Color:			Glass		Minimum or	rder quantity	/?	Yes	
opioid? Cannabinoid?	No No	Country of Origin India	1			Tube x Vial Liquid Sgl						
If Unit Dose, is item bar coded to u		Country of Origin India	Product Imprint:			Vial Liquid Sgi Vial Liquid Multi		If Yes. how	manv of wh	ich package t	type?	
scanning?		Is this product covered under the				Vial Powder Sql			Each			
If Unit Dose, indicate NDC here:		Trade Agreements Act (TAA)? No				Vial Power Multi			Inner/Cartor	/Pack		
		FOR GENERIC DRUG PRODUCTS			비 드	Other: Write In			Case			
		FOR GENERIC DRUG PRODUCTS						1				
				orized Generic, other section	PHARMACY ORDER / BILL UNIT							
I. Orange Book Rating:	AP		fields ar	e not applicable					ng unit to pharmacy:			
II. Generic Equivalent to What Bra	and?: CAMPTOSAR					1 Vial			Each			
	DRUG SUPPLY	(CHAIN SECURITY ACT (DSCSA) INFORMATIO	N		(Write-in, e.g. 1 V	iai)			Gram Milliliter			
Does supplier meet DSCSA defini	tion of manufacturer?	Yes GLN:	037070000007			ITEN	I AND PACKING I	NFORMATION	N			
Is product exempt from DSCSA?		No		_	1		Dimensi					
If yes, select exemption: Other exemption - Write in:						Weight Lbs.	Dimensi	ons (US msm Width	Height	Volume (Cube)	# Pieces:	
Is product repackaged?		No If Yes, was	s original product purchased	_	Item/Each:	0.055	2.559	1.575	1.575	6.3479194	1	
Is product sold by manufacturer's		No direct from					2.559	1.575	1.575	6.3479194	1	
Has FDA granted waiver/exceptio	n/exemption for product?	No If yes, atta	ch documentation from FDA.		Box/Carton/Bund Inner Pack:	lle/				0		
	GTIN	AND HIBCC PRODUCT INFORMATION			Case:							
						0.551	3.1496	7.874	2.559	63.463073	10	
Saleable Unit of Measure	Quantity		GTIN-14	Unit of Use GTIN-14	Pallet:					0		
Item/Each Box/Carton/Bundle/Inner Pack	1		00370700169223									
X Case	10		10370700169220			COST INFORMATION			WHOLESAL	ER USE ONL	_Y:	
Pallet												
	┥ ┝───┥				Regular Cost Invoice Cost (WA	(C) (S)	¢1/ E/	Vendor #: Whsl. Code	<i>#</i> ·			
	1 1					, (*)	ψ1+.04	Fineline Co				
					As of date:		-					
μ												
*Please provide any additional inf		Attach copy of SAFETY DATA SHEET (SDS) or no	on hazard letter, PACKAGE INSEF See new p. 3 for Design			NG and BARCODE.						
Flease provide any additional inf	ormation on page 2.		See new p. 3 for Design	ateu Drop Snip Uniy.	Sig	jiature:		L				

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:							



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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: Constraint 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?				