

Standard Pharmaceutical Product Information (Rx Product Only)

							Intr	oduction T	ype:	New Item]		Final Version			Date:	20.JUL	Y.2020
				PRODUCT INFORMA	TION								SPECIAL HANDLI	ING AND STO	ORAGE REQ	UIREMENTS	S*	
Company Name:	AuroMedics Pharma	LLC						Appl	ication:	ANDA	a. Temperatu	re – Indic	ate the USP tempera	ature range f	or this produ	ict.		
Application Number for ND			device):		2	13278							ture Range	atare range i	Controlled R	loom – betwe	en 20 and 25	C (68° – 77° F
DUNS:	968961354										-		mperature Range Re	quirement				
Proprietary Name (If Applical		Name: II	rinotecan F	Hydrochloride Injection US	5 40ma/2m						ד		ite in)	quiternent	Store at 20°	to 25°C (68°	to 77°F) [see	
Selling Unit NDC:	55150-352-01	Name.	motecum	Individual Unit NDC:	5 40mg/2m	55150-352-01		UPC:	'355150352	012	+1	(111	ite inj			10 20 0 (00	10 // / / [300	
UDI				CVX Code:				K Code:			†1	Is this pr	oduct to be shipped t	to customers of	on ice?		No	
Description:	Irinotecan Hydrochlor	ride Injection LISP	2 40mg/2m	nL [20mg/mL] [Single Dos	o Viall						†	-	oduct to be shipped t				No	
Description.	minotectari riyaroomol		, tong/2m	ie [zonig/nie] [onigie bos	c viaij							13 113 21	budet to be shipped t		on ary loc :			
Active Ingredient(s):		Irinotecan Hydro	ochloride								b. Contact fo	r tempera	ture excursion ques	stions:				
5 ()		-										Name:	•		Steve Lucas			
URL for Additional Product In											11	Number			732-823-412			
Address:	279 Princeton-Hights	town Road				_	Address				1 1	Group E	-mail:		slucas@aur	obindousa.c	om	
City:	East Windsor					State:	NJ	Z	2ip:	08520								
Key Contact: Phone Number:	888-238-7880					Email: Fax:	732-355	- 0440			c. Special reg		for product in any s				No No	
Product Therapeutic Classifi		Antineenleetie e	a and of the	e Topoisomerase I Inhibito		Fax.	132-330	5-9449			1	Special I	eturns requirements	for this produ	ULY		INU	
Product Therapeutic Classin	incation:	Antineoplastic a	gent of the	Topoisomerase Tinnibilo	or class								f a a la) un right 2				No	
ADDITIONA	AL PRODUCT INFORM						PRODUCT	DESCRIPT	TION INFOR	MATION	a. Store prod		of sale) upright? product (unit of sale) from light?			No	
							TROBOOT	DEGON				FIOLECL	bioduct (dilit of sale) nom nym:				
Is the Product a legend device?			No								e. Shelf life:	المائذها ما	elf life at launch (if e	different).			24	Months Months
reverse numbered?			No			Size:		1 x 2R Mor	no SDV Vial			initiai sh	en me at launch (m	amerent):				wonths
co-licensed?			No										C	DRDER INFO	RMATION			
Is the Product		Direct-Ship Only				Strength:		40mg/2mL	[20mg/mL]									
Is the Product		Neither				Dosage Form	. .	LIQUID				Unit of S	ale		What is the		unit?	
						Desageren	••	LIGOID					Bottle		1 box of 1 vi			
If Unit Dose, is item bar code	ed to unit dose for hosp	ital scanning?										x	Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
						Product Shap	pe:	Vial Pack					Ampule		Minima			Vee
If Unit Dose NDC, indicate N	NDC here:							-					Glass Tube		Minimum o	rder quantit	, r	Yes
Country of Origin		India				Product Colo	or:						Vial Liquid Sql					
								Vial Liquid Multi		If Yes, how	many of wh	ich package t	vpe?					
Is this product covered under the Trade Agreements Act (TAA)? Product Imprint:							Vial Powder Sql			Each								
													Vial Power Multi			Inner/Cartor	n/Pack	
				FOR GENERIC DRUG PR									Other: Write In	-	1	Case		
				OR GENERIC DRUG PR	ODUCIS													
						Auth	norized Ger	neric	*If Authorize	ed Generic, other section			PHAR	MACY ORDE		т		
L Orange Beak Beting	AP					/////	1011200 001		fields are no		Rec. sell unit	to oustor						
I. Orange Book Rating: II. Generic Equivalent to What	7.0	Camptosar Injec	ction 20 mc	g/mL; 2 mL, 5 mL, and 15	ml fill volu	mes (Pfizer Inc.))				Tree. seit unit	1 vi		1	Rx billing u x	Each	acy.	
II. Generie Equivalent to Mila		Oumptosar injec	2011201119	Jine, 2 me, 0 me, and 10			/				(Write-in, e.g					Gram		
		DRUG	SUPPLY	CHAIN SECURITY ACT	(DSCSA) II	FORMATION					,,	,				Milliliter		
Does supplier meet DSCSA of		turer?		Yes	(BLN:							ITEM AI	ND PACKING	INFORMAT	ION		
Is product exempt from DSC	CSA?	-	No	<u>)</u>														
If yes, select exemption:										-			Weight Lbs.		nsions (US m	width	Volume (Cube)	# Pieces:
Other exemption - Write in: Is product repackaged?	:		No			f Yes, was origir	al produc	t nurohaca	d direct	_	Item:			Depth	Height			
Is product repackaged?	turer's exclusive distri	butor?	110	No		rom mfr?	iai proude	· pui chase			item.		0.06	1.59	2.56	1.5	6.1056	1
Has FDA granted waiver/exc				No		f yes, attach doo	umentatio	on from FD/	Α.		Box/Carton/E	Bundle/	0.977	10.28	3.39	2.40	100 570000	40
_			-								Inner Pack:		0.977	10.28	3.39	3.46	120.578232	12
				GTIN PRODUCT INFOR							Case:		5.119	11.22	8.268	7.677	712.171952	48
					Saleable								0.110		0.200			.0
0		-	v ite	Level	Unit			1	Quantity	GTIN-14	Pallet:		647.293	48	54.61	40	104851.2	5760
Serialized? If not, when?	Yes	n -	× 110	em iox/Carton/Bundle/Inner Pack	x	x 2D x 2D		Linear Linear	1 12	00355150352012 30355150352013	UPC:		Case:	503551503	52017			
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		F				2D		Linear				COST	INFORMATION			WHOLESAI	ER USE ONL	Y:
		F				2D		Linear										
						2D		Linear			Regular Cost				Vendor #:			
					2D Linear				Invoice Cost (WAC) (\$) \$14.5 Federal Excise Tax Per Unit of Sale			\$14.50	14.50 Whsl. Code #:					
└────												se Tax Pe	r Unit of Sale		Fineline Co	de:		
											As of date:				-			
							and letter 1	DACKAGE					DCODE		1			
*Please provide any addition	nal information on an	202	Atta	acti copy of SAFETY DAT	A SHEET	(SUS) or non haz				BEL AND PHOTO OF PR Drop Ship Only.	JUUGT PACKAGI					Muromroda	y penchalaiah	
Flease provide any addition	nai information on pag	je 2.					See ne	wp.storD	esignated D	nop snip only.		Signatur	e.			wuramredo	y perionalalah	



Standard Pharmaceutical Product Information (Page 2)

	nated Drop Ship Only Products, Please Use Page 3
MATERIAL	HAZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply):	
a. Cytotoxic? Yes	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	Aerosol Class; Identify NFPA Storage Level:
d. Does this product require special clean-up instructions? No	
(If yes, attach SDS with special instructions.)	Is the product a NIOSH hazardous drug? No
e. Does the product contain DEHP? No	If yes, indicate which:
· · · · · · · · · · · · · · · · · · ·	
Is this product regulated for shipment by DOT or IATA? No	
(if yes, answer a-e below and provide SDS)	
a. UN/Identification Number	
b. Proper Shipping Name	Hazardous Waste Identification
c. DOT Hazard Class	EPA Hazardous Waste Code:
d. Packing Group	
e. Inhalation Hazard?	
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS
Passenger	Is there a REMS on this product? No
Cargo	If Yes, is it managed with a pharmacy registry?
Passenger & Cargo	Website URL:
Is this a reportable quantity?	· · · · · · · · · · · · · · · · · · ·
RQ Threshold:	Comments / Details: (For example, iPledge program?)
Is this a marine pollutant?	ommenta's betains: (r'or example, in redge program:)
Is this product shipped utilizing an authorized DOT exception or Special Permit?	
(if yes, identify method below)	REMS: No
Limited Quantity	REMS Program Manager Name: Phone:
Consumer Commodity, ORM-D	Supplier Manages REMS registry exclusively:
Small Quantity (49 CFR 173.4)	Wholesale distributor support:
Special Permit; DOT-SP	Provider Name:
Special Provision (listed in Column 7 of 49 CFR 172.101);	Site Enrollment Number assigned DEA #:
SP#	
	NPI#:
ADD'L STORAGE INFORMATION	
Is the Product	Comments
Controlled Substance? No	
Controlled by State(s)? No	Registry: No
ARCOS Reportable? No	Registry Program Contact Name: Phone:
Schedule No. (inc. N for non-narcotic)	Comments
Controlled Substance Code	
Listed Chemical (List I or II) No	RETURN INSTRUCTIONS
If yes, indicate which:	
Is it a scheduled listed chemical product?:	Contact tel. # if product received damaged: 888-238-7880
CLASS OF TRADE RESTRICTION:	Is product returnable for credit:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	URL/Link to returns policy: http://auromedics.com/policies/return-policy/
Restricted to retail pharmacy only: No	Special regulations or returns requirements for this product in certain states?
Restricted to hospital, clinics, and physician offices only: No	If so, which states? Other requirements? Comments?
Restricted from US territories? (explain in comments) No	
Comments:	
MISCELLA	NEOUS NOTES and/or Image of Product Barcode:



Standard Pharmaceutical Product Information (Page 3)

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if	
Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI b. Autofax Fax Number: c. Fax Fax Number: d. Phone only Phone No.: e. Supplier Web Site only Site Address: Minimum Order Quantity:	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 Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:	Overnight receipt available:
	Priority Overnight receipt available:
Class of Trade Restriction: 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:	PO Receipt Cut off time:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	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?



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							Introduct	tion Type:	New Item			Final Version			Date:	20.JUL	Y.2020
				PRODUCT INFORMA	ATION							SPECIAL HANDL	ING AND ST	ORAGE REQ	JIREMENTS	5*	
	Company Name:	AuroMedics Pharma	LLC					Application:	ANDA		a. Temperature – Indic	ate the USP temper	rature range f	or this produ	ct.		
				vice):	213	278							j- ·			en 20 and 25	C (68° – 77° F
												-	quirement				
			Name: Irinot	ecan Hydrochloride Injection II	ISP 100 mg/5m	nl							equilement	Store at 20°	to 25°C (68°	to 77°F) [see	
			inite.				UE	PC: 355150	353019		(ite itiy		01010 41 20	00) 0 0120	10 11 1 / [000	
Description: inclusion inclusions for iterations in the inclusion of iteration					· · · ·						Is this pr	oduct to be shipped t	to customers of	on ice?		No	
<form></form>	Description:	Irinotecan Hydrochlor	ide Injection LISP 10	0 ma/5ml [20ma/ml]][Sinale D	Jose Viall					=	-					No	
	Description.	minoteccaminyurocinio		, mg/onie (zomg/nie) (omgie b	Jose viaij						is this product to be shipped to customers on dry ice? No						
	Active Ingredient(s):		Irinotecan Hydrochlo	vride							b. Contact for tempera	ture excursion ques	stions:				
											Name:			Steve Lucas			
	/ luar oco:		town Road								Group E	-mail:		slucas@auro	obindousa.co	om	
		East Windsor					NJ	Zip:	08520							N	
Product Transported Caskellisetion: ADD/TOUGLY INFORMATION Is the Product. Biter product Que of the Database of		888-238-7880					732-355-0440	0						a+2			
			Antineoplastic agent	t of the Topoisomerase I Inhibit	tor class	Tax.	732-333-3443	-5			Special	eturns requirements		ur		INU	
ACCENTIONAL RECORD TANGONATION Product Table Product. No Is the Product. No No No Size: 1 & K More GOV /vig No No No Size: 1 & K More GOV /vig No No No No Size: 1 & K More GOV /vig No No No No No It No Product. No Inter No No <td< td=""><td>Froduct merapeutic classifi</td><td></td><td>Antineoplastic agent</td><td>or the ropoisonerase rinnibit</td><td>101 01833</td><td></td><td></td><td></td><td></td><td></td><td>d Store product (unit</td><td>of cale) upright?</td><td></td><td></td><td></td><td>No</td><td></td></td<>	Froduct merapeutic classifi		Antineoplastic agent	or the ropoisonerase rinnibit	101 01833						d Store product (unit	of cale) upright?				No	
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IL Unito toos NDC, indicate NDC here:	If Unit Dose, is item bar code	ed to unit dose for hosp	ital scanning?								x	+		(Write-in, e.	g. 1 Box of 1	0 Vials)	
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It mig product coveres under the finder appendence of (1Ay) Product imprime I or ange Book Rating: AP I. Orange Book Rating: AP I. Orange Book Rating: Appendence of product of produ	Country of Origin India Product Color:									Vial Liquid Sgl							
Image: Control Contro Control Control Control Control Control Control Control Control C										Vial Liquid Multi		If Yes, how	many of wh	ich package t	ype?		
In the calculation of manufacturer? No If watch or goal of an interval of and introduces (PBzer, Inc.) Decession and applicable In Conception Bock Rating: PLANMACY ORDER / BLL UNT In Conception Bock Rating: PLANMACY ORDER / BLL UNT In Conception Bock Rating: PLANMACY ORDER / BLL UNT In Conception Bock Rating: PLANMACY ORDER / BLL UNT In Conception Bock Rating: In Witchine of manufacturer? Yes GLN: In Witchine of manufacturer? Res bit watch of the min // Witchine of manufacturer? No GLN: In Witchine of manufacturer? No Vision min // Witchine of manufacturer? No If Yes, was original product purchased direct In Witchine of the min // Witchine of the min /	is this product covered under	The Hade Agreement										• •					
POR GENERIC DRUG PRODUCTS Authorized Generic, "If																n/Pack	
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1. Orange Bock Reting: AP																	
Comparing Each Rating: Performation reconstruction of manufacture of a rank and 15 mL fill volumes (Plazer, inc.) Resultant output					I	Author	ized Generic	*If Autho	orized Generic, other section	on		PHAR	RMACY ORDE	R / BILL UNI	Т		
II. Generic Equivalent to What Brand?: Camptosar linjention 20 mg/mL; 2 mL, 5 mL, and 15 mL, fill volumes (Pitzer, Inc.) 1 viai x Each condition of manufacture? Yes GLN: Item to the second to the	I. Orange Book Rating:	AP			٦ '					F	Rec. sell unit to custor	ner?		Rx billing u	nit to pharm	acv:	
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION Dees supplier mer DSCSA (finition of manufacturer? Yes GLN: ITEM AND PACKING INFORMATION Dees supplier mer DSCSA? No No ITEM AND PACKING INFORMATION Volume # Pieces: Other scemption: Dimensions (US msmts.) Dimensions (US msmts.) Volume # Pieces: Is product reackaged? No If Yes, select scemption: Dimensions (US msmts.) Volume # Pieces: Is product reackaged? No If Yes, select scemption: Dimensions (US msmts.) Volume # Pieces: Serialized? No If yes, select scemption: Dime Dimensions (US msmts.) Volume # Pieces: Serialized? Yes Imm Saleable Dime Dimensions (US msmts.) Volume # Pieces: Serialized? Yes Imm X 20 Linear 1 Diasoff 10033010 UPC: Case: 50356150333014 UPC: Case: 50356150333014 UPC: Case: So35150333014 UPC: Case: So35150333014 </td <td></td> <td>at Brand?:</td> <td>Camptosar Injection</td> <td>20 mg/mL; 2 mL, 5 mL, and 15</td> <td>5 mL fill volume</td> <td>es (Pfizer, Inc.)</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>-</td> <td></td> <td></td> <td></td>		at Brand?:	Camptosar Injection	20 mg/mL; 2 mL, 5 mL, and 15	5 mL fill volume	es (Pfizer, Inc.)								-			
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Is product oue exemption: Dimensions (US marks) Volume # Plees: If yes, select exemption: No If Yes, was original product purchased direct from mfr? No If Yes, was original product purchased direct from mfr? No If Yes, stach documentation from FDA. No If Yes, stach documentation from FDA. Is product obly manufacture's exclusive distributor? No If yes, stach documentation from FDA. No If Yes, stach documentation from FDA. No If Yes, stach documentation from FDA. Serialized? Yes X Saleable Quantity GTIN-14 10.28 3.39 3.46 120.5782.32 12 Serialized? Yes X BookCator/Vieundelmer Pak, X X 20 Linear 1 0035515035019 UPC: Case: 5035510335014 UPC: Case: 5035			DRUG SUI	PPLY CHAIN SECURITY ACT	(DSCSA) INFO	ORMATION									Milliliter		
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If yes, select exemption: Image: Select			urer?		GLN	N:						IIEMA	ND PACKING	INFORMATI	ON		
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Is product repackaged? No If Yes, was original product purchased direct Is product sold by manufacturer's exclusive distributor? No if wes, was original product purchased direct Has FDA granted waiver/exception/except												Weight Lbs.					# Pieces:
Is product sold by manufacturer's exclusive distributor? No from mfr? Has FDA granted waiver/exception/exceptin/exceptin/exception/exception/exceptin/exception/exc	Is product repackaged?			No			product purc	chased direct			Item:	0.08	-	-	1.5	6 1056	1
GTIN PRODUCT INFORMATION Seleable Level Unit Quantity GTIN-14 GTIN-14 Case 6.175 11.22 8.268 7.677 712.171952 48 Serialized? Yes X Item X 2D Linear 1 030355150353010 030355150353010 UPC: Case: 6.175 11.22 8.268 7.677 712.171952 48 Items aggregated? Yes X Dew Cartor/Bundle/Inner Pack X 2D Linear 1 030355150353010 50355100 00355150353014 UPC: Case: 60355150353014 UPC: Case: 00355150353013 UPC: Case: 00355150353014 UPC: Case: Vendor #: Ime Ime <td></td> <td></td> <td></td> <td></td> <td>_</td> <td></td> <td></td> <td></td> <td></td> <td>_</td> <td></td> <td>0.00</td> <td>1.55</td> <td>2.50</td> <td>1.5</td> <td>0.1000</td> <td></td>					_					_		0.00	1.55	2.50	1.5	0.1000	
GTIN PRODUCT INFORMATION Seleable Level Unit Case: 6.175 11.22 8.268 7.677 712.171952 48 Serialized? Yes T Case: 6.175 11.22 8.268 7.677 712.171952 48 Serialized? Yes T 0 Colspan="6">6.175 11.22 8.268 7.677 712.171952 48 If not, when? T T 0 Colspan="6">Case: 60355150353014 X 20 Linear T X 20 Linear Colspan="6" T																	



Standard Pharmaceutical Product Information (Page 2)

	nated Drop Ship Only Products, Please Use Page 3
MATERIAL	HAZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply):	
a. Cytotoxic? Yes	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	Aerosol Class; Identify NFPA Storage Level:
d. Does this product require special clean-up instructions? No	
(If yes, attach SDS with special instructions.)	Is the product a NIOSH hazardous drug? No
e. Does the product contain DEHP? No	If yes, indicate which:
· · · · · · · · · · · · · · · · · · ·	
Is this product regulated for shipment by DOT or IATA? No	
(if yes, answer a-e below and provide SDS)	
a. UN/Identification Number	
b. Proper Shipping Name	Hazardous Waste Identification
c. DOT Hazard Class	EPA Hazardous Waste Code:
d. Packing Group	
e. Inhalation Hazard?	
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS
Passenger	Is there a REMS on this product? No
Cargo	If Yes, is it managed with a pharmacy registry?
Passenger & Cargo	Website URL:
Is this a reportable quantity?	· · · · · · · · · · · · · · · · · · ·
RQ Threshold:	Comments / Details: (For example, iPledge program?)
Is this a marine pollutant?	ommenta's betains: (r'or example, in redge program:)
Is this product shipped utilizing an authorized DOT exception or Special Permit?	
(if yes, identify method below)	REMS: No
Limited Quantity	REMS Program Manager Name: Phone:
Consumer Commodity, ORM-D	Supplier Manages REMS registry exclusively:
Small Quantity (49 CFR 173.4)	Wholesale distributor support:
Special Permit; DOT-SP	Provider Name:
Special Provision (listed in Column 7 of 49 CFR 172.101);	Site Enrollment Number assigned DEA #:
SP#	
	NPI#:
ADD'L STORAGE INFORMATION	
Is the Product	Comments
Controlled Substance? No	
Controlled by State(s)? No	Registry: No
ARCOS Reportable? No	Registry Program Contact Name: Phone:
Schedule No. (inc. N for non-narcotic)	Comments
Controlled Substance Code	
Listed Chemical (List I or II) No	RETURN INSTRUCTIONS
If yes, indicate which:	
Is it a scheduled listed chemical product?:	Contact tel. # if product received damaged: 888-238-7880
CLASS OF TRADE RESTRICTION:	Is product returnable for credit:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	URL/Link to returns policy: http://auromedics.com/policies/return-policy/
Restricted to retail pharmacy only: No	Special regulations or returns requirements for this product in certain states?
Restricted to hospital, clinics, and physician offices only: No	If so, which states? Other requirements? Comments?
Restricted from US territories? (explain in comments) No	
Comments:	
MISCELLA	NEOUS NOTES and/or Image of Product Barcode:



Standard Pharmaceutical Product Information (Page 3)

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if	
Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI b. Autofax Fax Number: c. Fax Fax Number: d. Phone only Phone No.: e. Supplier Web Site only Site Address: Minimum Order Quantity:	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 Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:	Overnight receipt available:
	Priority Overnight receipt available:
Class of Trade Restriction: 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:	PO Receipt Cut off time:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	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?



Standard Pharmaceutical Product Information (Rx Product Only)

							Intr	oduction Ty	ype:	New Item	I		Final Version			Date:	20.JUL	Y.2020
				PRODUCT INFORMA	TION								SPECIAL HANDLI	NG AND STO	DRAGE REQ	UIREMENTS	*	
Company Name:	AuroMedics Pharma	LLC						Appl	ication:	ANDA	a. Temperat	ure – Indic	ate the USP tempera	ature range f	or this produ	ict.		
Application Number for ND	A/ANDA/BLA (drug);	PMA/510(k)(med	device):		2	13278					1		ture Range		Controlled F	toom – betwe	en 20 and 25	C (68° – 77° F
DUNS:	968961354											Other Te	mperature Range Re	auirement				
Proprietary Name (If Applical	able) and Established	Name: II	Irinotecan Hy	drochloride Injection US	SP, 300 mg/	15mL					וד	(wr	ite in)		Store at 20°	to 25°C (68°	to 77°F) [see	
Selling Unit NDC:	55150-354-01			Individual Unit NDC:		55150-354-01			'355150354	016	11							
UDI				CVX Code:			MV)	X Code:]	Is this pr	oduct to be shipped to	o customers o	on ice?		No	
Description:	Irinotecan Hydrochlor	ide Injection USP	o, 300 mg/15	imL [20mg/mL] [Single [Dose Vial]							Is this pr	oduct to be shipped to	o customers o	on dry ice?		No	
Active Ingredient(s): Irinotecan Hydrochloride							b. Contact for temperature excursion questions: Name: Steve Lucas											
URL for Additional Product I	Information.										41	Number			732-823-412			
Address:	279 Princeton-Hights	town Road					Address	s 2:			11	Group E			slucas@aur		m	
City:	East Windsor					State:	NJ		Zip:	08520	11							
Key Contact:						Email:					c. Special re		for product in any st				No	
Phone Number:	888-238-7880					Fax:	732-355	5-9449			11	Special I	returns requirements f	for this produc	ct?		No	
Product Therapeutic Classifi	ication:	Antineoplastic a	igent of the T	Topoisomerase I Inhibito	or class						d Store pro	duct (unit	of sale) upright?				No	
ADDITIONA	AL PRODUCT INFORM						PRODUCT	DESCRIPT	TION INFOR	MATION	u. Store pro		product (unit of sale) from light?			No	
Is the Product											e. Shelf life:			,			24	Months
a legend device?		Ν	No								e. onen me.		elf life at launch (if o	different)			24	Months
reverse numbered?			No			Size:		1 x 20R Mc	ono SDV Via	I		initial of						monuto
co-licensed?			No			Strength:		300 mg/15	mL [20mg/m	11			0	RDER INFOR	RMATION			
Is the Product		Direct-Ship Only	у			ou engin.		000 mg/10	ine (zoing/in									
Is the Product		Neither				Dosage Form	n:	LIQUID				Unit of S	Sale Bottle		What is the 1 box of 1 v	NDC selling	unit?	
												x	Box/Carton			g. 1 Box of 1	0 Vials)	
If Unit Dose, is item bar code	ed to unit dose for hosp	ital scanning?				Product Shar	<u>.</u>	Vial Pack					Ampule		(, .	5	,	
If Unit Dose NDC, indicate N	IDC here:					i i ouuot onu		viai i doit					Glass		Minimum o	rder quantity	?	Yes
Country of Origin		India				Product Colo	er:						Tube Vial Liquid Sql					
, ,	r the Trade Agreement	. Act (TAA)2				Product Impr	int.						Vial Liquid Multi		If Yes, how	many of wh	ich package t	ype?
Is this product covered under the Trade Agreements Act (TAA)?					Vial Powder Sql Each													
					L						1		Vial Power Multi Other: Write In		1	Inner/Cartor Case	/Pack	
			FO	OR GENERIC DRUG PR	ODUCTS								Other: white in	Т		Case		
						Auth	norized Ger			ed Generic, other section			PHAR	MACY ORDE	R / BILL UN	T		
in orange Been nanng.	AP								fields are no	ot applicable	Rec. sell un			-	Rx billing u	nit to pharm	acy:	
II. Generic Equivalent to What	at Brand?:	Camptosar Injec	ction 20 mg/n	mL; 2 mL, 5 mL, and 15	mL fill volu	mes (Pfizer, Inc.))					1 vi	al		x	Each Gram		
		DRUG	S SUPPLY C	HAIN SECURITY ACT	(DSCSA) IN	FORMATION		-			(Write-in, e.	g. 1 viai)				Gram Milliliter		
					,													
Does supplier meet DSCSA of		urer?	No	Yes	G	LN:							ITEM AN	ND PACKING	INFORMAT	ION		
Is product exempt from DSC If yes, select exemption:	5A?		INU											Dimer	nsions (US n	smts.)	Volume	
Other exemption - Write in:										1			Weight Lbs.	Depth	Height	Width	(Cube)	# Pieces:
Is product repackaged?		-	No			Yes, was origin	nal produc	t purchase	d direct		Item:		0.14	1.81	3.35	1.65	10.004775	1
Is product sold by manufactu Has FDA granted waiver/exc				No No		om mfr? yes, attach doo	umontotio	n from ED			Box/Carton/	/Bundlo/						
Thas I DA granted warver/exc	seption/exemption for			110		yes, attach dot	umentatio		.		Inner Pack:		2.02	11.65	4.17	3.78	183.63429	12
			G	TIN PRODUCT INFOR							Case:		9.268	12.598	9.843	8.465	1049.6779	48
					Saleable								5.200	12.000	5.040	0.400	1040.0110	-
Serialized?	Ves	г	x Item	Level	Unit x	X 2D		Linear	Quantity 1	GTIN-14 00355150354016	Pallet:		774.47	48	54.21	40	104083.2	3840
If not, when?	103	1 F		/Carton/Bundle/Inner Pack	<u>^</u>	x 2D	-	Linear	12	30355150354017	UPC:		Case:	5035515035	54011			
Items aggregated?		1 1	X Case	e		X 2D		Linear	48	50355150354011			Carton:	0035515035				
		- [x Palle	et		X 2D		Linear	3840	70355150354015								
						2D		Linear				COST	INFORMATION			WHOLESAL	ER USE ONL	Y:
		F				2D 2D		Linear Linear			Regular Co				Vendor #:			
						2D 2D		Linear			Regular Cost Invoice Cost (WAC) (\$) \$100.0				Whsl. Code	#:		
					20 Linear				Federal Excise Tax Per Unit of Sale			φ100.00	Fineline Co					
											As of date:				1			
a Diana a su di	*Please provide any additional information on page 2. Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODU							ODUCT PACKAG					M					
*Please provide any addition	nal information on pag	je 2.					See nev	N p. 3 for D	esignated D	prop Ship Only.		Signatu	re:			Muramredd	y penchalaiah	



Standard Pharmaceutical Product Information (Page 2)

	nated Drop Ship Only Products, Please Use Page 3
MATERIAL	HAZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply):	
a. Cytotoxic? Yes	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
Does the product laber bear a CA Prop 65 warning?	Contact Hazard
c. Contact Hazard? No	Aerosol Class; Identify NFPA Storage Level:
d. Does this product require special clean-up instructions? No	
(If yes, attach SDS with special instructions.)	Is the product a NIOSH hazardous drug? No
e. Does the product contain DEHP? Yes	If yes, indicate which:
Is this product regulated for shipment by DOT or IATA? No	
(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:
d. Packing Group	
e. Inhalation Hazard?	
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS
Passenger	Is there a REMS on this product? No
Cargo	If Yes, is it managed with a pharmacy registry?
Passenger & Cargo	white the set of the s
	Website UKL.
Is this a reportable quantity?	
RQ Threshold:	Comments / Details: (For example, iPledge program?)
Is this a marine pollutant?	
Is this product shipped utilizing an authorized DOT exception or Special Permit?	
(if yes, identify method below)	REMS: No
Limited Quantity	REMS Program Manager Name: Phone:
Consumer Commodity, ORM-D	Supplier Manages REMS registry exclusively:
Small Quantity (49 CFR 173.4)	Wholesale distributor support:
Special Permit; DOT-SP	Provider Name:
Special Provision (listed in Column 7 of 49 CFR 172.101);	Site Enrollment Number assigned DEA #:
SP#	by Supplier: PCPDP #:
	NPI#:
ADD'L STORAGE INFORMATION	
Is the Product	Comments
Controlled Substance? No	
Controlled by State(s)? No	Registry: No
ARCOS Reportable? No	Registry Program Contact Name: Phone:
Schedule No. (inc. N for non-narcotic)	Comments
Controlled Substance Code	
Listed Chemical (List I or II) No	RETURN INSTRUCTIONS
If yes, indicate which:	Contact tel. # if product received damaged: 888-238-7880
Is it a scheduled listed chemical product?:	Contact tel. # if product received damaged: 888-238-7880
CLASS OF TRADE RESTRICTION:	Is product returnable for credit:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	URL/Link to returns policy: http://auromedics.com/policies/return-policy/
Restricted to retail pharmacy only: No	Special regulations or returns requirements for this product in certain states?
Restricted to hospital, clinics, and physician offices only: No	If so, which states? Other requirements? Comments?
Restricted from US territories? (explain in comments) No	
Comments:	
MISCELLA	NEOUS NOTES and/or Image of Product Barcode:



Standard Pharmaceutical Product Information (Page 3)

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if	
Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI b. Autofax Fax Number: c. Fax Fax Number: d. Phone only Phone No.: e. Supplier Web Site only Site Address: Minimum Order Quantity:	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 Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:	Overnight receipt available:
	Priority Overnight receipt available:
Class of Trade Restriction: 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:	PO Receipt Cut off time:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	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?