

							Intro	duction Ty	pe:	New Item		Final Version			Date:					
				PRODUCT INFORMA	TION							SPECIAL HANDLI	NG AND STO	RAGE REQU	JIREMENTS	5*				
Company Name:	AuroMedics Pharma L	LC						Applic	cation:	ANDA	a. Temperature – Indi	cate the USP tempera	ature range fo	or this produ	ct.					
Application Number for ND	A/ANDA/BLA (drug); I	PMA/510(k)(med	device):		02	206918	•		'		Tempe	rature Range	-	Controlled R	oom – betwe	en 20 and 25	C (68° - 77° I			
DUNS:	968961354										Other T	emperature Range Re	quirement							
Proprietary Name (If Applical	ble) and Established I	Name: F	ondaparir	nux Sodium Injection, USI	P 2.5 mg per	0.5 mL (10's)						vrite in)	•							
Selling Unit NDC:	55150-230-10			Individual Unit NDC:		55150-230-00			3551502301	05							_			
UDI				CVX Code:			MVX	Code:			Is this p	Is this product to be shipped to customers on ice?								
Description:	Fondaparinux Sodium	n Injection, USP 2.	.5 mg per	0.5 mL (10's)							Is this p	product to be shipped t	o customers o	n dry ice?						
Active Ingredient(s):											b. Contact for temper	ature excursion ques	tions:							
LIDI for Additional Draduct I	-fti	www.auromedics	m								Name:									
URL for Additional Product II Address:	279 Princeton-Hightst		s.com			1	Address	2.			Numbe Group									
City:	East Windsor	.omi i toda				State:	NJ	-· L	ip:	08520	- I	L man.								
Key Contact:						Email:					c. Special regulations	s for product in any s	tates?			No				
Phone Number:	888-238-7880					Fax:	732-355-	9449			Special	returns requirements	for this produc	t?		No				
Product Therapeutic Classifi	cation:																			
											d. Store product (unit					Yes				
ADDITIONA	L PRODUCT INFORM	ATION					PRODUCT	DESCRIPTI	ION INFORM	MATION	Protect	t product (unit of sale) from light?			No	•			
Is the Product							_				e. Shelf life:			24			Months			
a legend device?			10			Size:		1 PFS Unit			Initial s	shelf life at launch (if	different):				Months			
reverse numbered?			10				_													
co-licensed? Is the Product		Direct-Ship Only	10			Strength:	2	2.5 mg per (0.5 mL			U	RDER INFOR	MATION						
Is the Product		Direct Only Only					-				Unit of Sale What is the NDC selling unit?									
						Dosage Form	ı: l	LIQUID			Bottle S5150-230-10 1 box of 10 pre-filled syri						ringes			
If Unit Dose, is item bar code	d to unit does for bosn	ital ecanning?									x	Box/Carton		(Write-in, e.g	g. 1 Box of 1	0 Vials)				
		itai scaiiiiig:				Product Shape: PFS (Pre filled						Ampule								
If Unit Dose NDC, indicate NI	DC here:										Glass Minimum order quantity?									
Country of Origin	Product Color:						Tube Vial Liquid Sgl													
Country of Origin								Vial Liquid Sgi Vial Liquid Multi		If Yes how	many of wh	ich package	tvne?							
Is this product covered under the Trade Agreements Act (TAA)?				Product Imprint:					Vial Powder Sql			1 Each								
<u> </u>					Vial Power Multi 10 Inner/Carton/Pack															
												Other: Write In	_	80	Case					
			F	FOR GENERIC DRUG PR	RODUCTS															
						Auth	orized Gene	orio *	*If Authorized	d Generic, other section		PHAR	MACY ORDE	R / BILL LINE	т					
I Owner Bank Barting	AP				1	Addi	onzed Gen		fields are not		Rec. sell unit to custo									
I. Orange Book Rating: II. Generic Equivalent to Wha	, ···	Arixtra Injection									Rec. sell unit to custo	1	Rx billing unit to pharmacy: Each							
ii. Generic Equivalent to Wha	it Dianu:.	Anxila Injection									(Write-in, e.g. 1 Vial)		_		Gram					
		DRUG	SUPPLY	CHAIN SECURITY ACT	(DSCSA) IN	FORMATION					(**************************************				Milliliter					
Does supplier meet DSCSA of		urer?		Yes	G	LN:	0355150	000005				ITEM A	ND PACKING	INFORMATI	ON					
Is product exempt from DSC	SA?		N	0	-								Dimon	sions (US m	omto \					
If yes, select exemption: Other exemption - Write in:										•		Weight Lbs.	Depth	Height	Width	Volume (Cube)	# Pieces:			
Is product repackaged?			N	0	If	Yes, was origin	al product	purchased	direct		Item:		Бери	ricigiit	Wide					
Is product sold by manufactu	urer's exclusive distri	butor?		No		om mfr?										0				
Has FDA granted waiver/exce	eption/exemption for	product?		No	If	yes, attach doc	umentation	n from FDA	١.		Box/Carton/Bundle/	5.0926	14.41	7.48	8.9	959.30252	one E-Flute b			
											Inner Pack:	0.0020		7.10	0.0	000.00202	0.10 2 1 1010 0			
				GTIN PRODUCT INFOR	MATION Saleable						Case:	6.536	15.551	9.055	9.843	1386.0352	box, 1 E-Flute			
				Level	Unit			(Quantity	GTIN-14	Pallet:	Sea: 346.775		Sea: 41.22			SEA.			
Serialized?			x II	tem	х	2D		Linear		10355150230102	I dilet.	Air: 425.212	48	Air: 50.28	40	#VALUE!	10 PFS in			
If not, when?		1 -		Box/Carton/Bundle/Inner Pack		2D		Linear	80	30355150230106	UPC:	Case:	5035515023	0100			Canon A			
Items aggregated?				Case		2D		Linear	80	50355150230100		Carton:	1035515023	0102						
			X F	Pallet	Щ	2D			4800	70355150230104		T INCODE ATION			WIIOI = 0	ED HOE OW	v			
		<u> </u>				2D 2D	\vdash	Linear			cos	TINFORMATION			WHOLESAL	ER USE ONL	.Y:			
		⊢	 ⊦			2D 2D	\vdash	Linear			Regular Cost			Vendor #:						
	2D Linear					Invoice Cost (WAC) (S	\$)	\$240.00	Whsl. Code	#:										
											Federal Excise Tax P		Fineline Code:							
	_										As of date:	1/17/2018								
			Att	tach copy of SAFETY DAT	TA SHEET (SDS) or non haz					ODUCT PACKAGING and									
*Please provide any addition	al information on pag	je 2.					See new	p. 3 for De	esignated Dr	rop Ship Only.	Signate	ure:								





Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI	Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax Fax Number: c. Fax d. Phone only e. Supplier Web Site only Fax Number: Fax Num	Shipping lead time of PO: Hours Days Ships same day for next day receipt:
Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	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:
Drop Ship service fee billed with each order:	PO Receipt cut off time:
Drop Ship miscellaneous fees billed: Comments:	Days of week overnight is available: Monday 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 physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
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?



							Intro	duction Typ	oe:	New Item		Final Version			Date:				
				PRODUCT INFORMA	ATION							SPECIAL HANDLI	NG AND STO	RAGE REQU	JIREMENTS	5*			
Company Name:	AuroMedics Pharma L	LC						Applic	ation:	ANDA	a. Temperature - Indic	cate the USP tempera	ature range fo	or this produ	ct.				
Application Number for ND	A/ANDA/BLA (drug); F	PMA/510(k)(med	device):		0:	206918			•		Temper	ature Range	-	Controlled R	oom – betwe	en 20 and 25	C (68° - 77° I		
DUNS:	968961354										Other To	emperature Range Re	quirement						
Proprietary Name (If Applical	ble) and Established I	Name: Fo	ondaparir	nux Sodium Injection, US	P 5 mg per 0	0.4 mL (10's)						rite in)	•						
Selling Unit NDC:	55150-231-10			Individual Unit NDC:		55150-231-00			35515023110)2							_		
UDI				CVX Code:			MVX	Code:			Is this p	roduct to be shipped to	o customers o	n ice?					
Description:	Fondaparinux Sodium	Injection, USP 5	mg per 0).4 mL (10's)							Is this p	roduct to be shipped to	o customers o	n dry ice?					
Active Ingredient(s):											b. Contact for tempera	ature excursion ques	tions:						
LIDI for Additional Draduct I	-f	www.auromedics									Name:								
URL for Additional Product II Address:	279 Princeton-Hightst		S.COIII				Address	2.			Number Group I								
City:	East Windsor	.omi rtoda				State:	NJ	-· L	o: (08520	1	u							
Key Contact:						Email:					c. Special regulations	for product in any st	tates?			No			
Phone Number:	888-238-7880					Fax:	732-355-	9449			Special	returns requirements f	for this produc	t?		No			
Product Therapeutic Classifi	cation:																		
						_					d. Store product (unit					Yes	_		
ADDITIONA	L PRODUCT INFORM	ATION				ı	PRODUCT	DESCRIPTI	ON INFORM	ATION	Protect	product (unit of sale) from light?			No	•		
Is the Product							_				e. Shelf life:						Months		
a legend device?		<u>N</u>				Size:	1	1 PFS Unit			Initial s	helf life at launch (if o	different):				Months		
reverse numbered?		N					L												
co-licensed? Is the Product		Direct-Ship Only				Strength:	5	5 mg per 0.4	mL			0	RDER INFOR	MATION					
Is the Product		Direct Only Only					-				Unit of Sale What is the NDC selling unit?								
						Dosage Form	i: L	LIQUID				Bottle		55150-231-10 1 box of 10 pre-filled syringes					
If Unit Dose, is item bar code	d to unit does for bosni	ital ecanning?					_				х	Box/Carton		(Write-in, e.g	g. 1 Box of 1	0 Vials)			
		itai scailing:				Product Shap	e: F	PFS (Pre filled syringe)				Ampule							
If Unit Dose NDC, indicate NI	DC here:					- (Glass Minimum order quantity?								
Country of Origin	Country of Origin India Product Color:						Tube Vial Liquid Sgl												
							Vial Liquid Sgi Vial Liquid Multi		If Yes how	many of wh	ich package t	tvne?							
Is this product covered under the Trade Agreements Act (TAA)?			Product Impr	int:					Vial Powder Sql			Each							
<u></u>					Vial Power Multi 10 Inner/Carton/Pack														
												Other: Write In	_	80	Case				
			F	FOR GENERIC DRUG PR	RODUCTS														
						Auth	orized Gene	oric *I	If Authorized	Generic, other section		PHAR	MACY ORDE	R/BILL LINE	Т				
I Owner Bank Barting	AP				7	Auti	onzeu Gene		elds are not		Rec. sell unit to custo								
I. Orange Book Rating: II. Generic Equivalent to Wha	7 (Arixtra Injection									Rec. sell unit to custo	iller r	1	Rx billing ur	Each	acy:			
ii. Generie Equivalent to Wha	it Diulia	Allixila Injection									(Write-in, e.g. 1 Vial)		_		Gram				
		DRUG S	SUPPLY	CHAIN SECURITY ACT	(DSCSA) IN	IFORMATION					, , ,				Milliliter				
											,								
Does supplier meet DSCSA of		urer?		Yes	_ G	iLN:	03551500	000005				ITEM AN	ND PACKING	INFORMATI	ON				
Is product exempt from DSC If yes, select exemption:	SA?		N	10	_								Dimon	sions (US m	emte \	Volume			
Other exemption - Write in:									ĺ			Weight Lbs.	Depth	Height	Width	(Cube)	# Pieces:		
Is product repackaged?			N	lo	If	Yes, was origin	al product	purchased	direct		Item:			11019111	*******				
Is product sold by manufactu	urer's exclusive distril	butor?		No		om mfr?			-							0			
Has FDA granted waiver/exce	eption/exemption for	product?		No	_ If	yes, attach doc	umentation	n from FDA.			Box/Carton/Bundle/	5.0926	14.41	7.48	8.9	959.30252	one E-Flute b		
				GTIN PRODUCT INFOR	MATION						Inner Pack:								
				GTIN PRODUCT INFOR	Saleable						Case:	6.536	15.551	9.055	9.843	1386.0352	box, 1 E-Flute		
				Level	Unit			C	Quantity	GTIN-14	Pallet:	Sea: 346.775		Sea: 41.22			SEA.		
Serialized?			x II	Item	x	2D		Linear		10355150231109	I unct.	Air: 425.212	48	Air: 50.28	40	#VALUE!	10 PFS in		
If not, when?		1		Box/Carton/Bundle/Inner Pack		2D		Linear		30355150231103	UPC:	Case:	5035515023	1107			Canon A		
Items aggregated?				Case		2D		Linear		50355150231107		Carton:	1035515023	1109					
			X F	Pallet	—— [2D		_	4800	70355150231101	2007	INCORMATION			MUOLEO H	ED HOE ON	V		
		-	—— -		\vdash	2D 2D		Linear			Cost	INFORMATION			WHOLESAL	ER USE ONL	.Y:		
		<u> </u> -	 - ⊦		\vdash	2D 2D		Linear			Regular Cost			Vendor #:					
	2D Linear					Invoice Cost (WAC) (\$)	\$581.00	Whsl. Code	#:									
															Fineline Code:				
	_	-								_	As of date:	1/17/2018							
			Att	tach copy of SAFETY DA	TA SHEET (SDS) or non haz					DDUCT PACKAGING and E								
*Please provide any addition	al information on pag	je 2.					See new	p. 3 for De	signated Dro	op Ship Only.	Signatu	ire:							





Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI	Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax Fax Number: c. Fax d. Phone only e. Supplier Web Site only Fax Number: Fax Num	Shipping lead time of PO: Hours Days Ships same day for next day receipt:
Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	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:
Drop Ship service fee billed with each order:	PO Receipt cut off time:
Drop Ship miscellaneous fees billed: Comments:	Days of week overnight is available: Monday 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 physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
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?



					Introduction	n Type:	New Item		Final Version			Date:			
			PRODUCT INFORMATION						SPECIAL HANDLI	NG AND STO	ORAGE REQU	JIREMENTS	*		
Company Name:	AuroMedics Pharma L	LC			Α	pplication:	ANDA	a. Temperature – Indic	ate the USP tempera	ature range f	or this produ	ct.			
Application Number for ND	A/ANDA/BLA (drug); F	PMA/510(k)(med device):		0206918	•			Tempera	ature Range		Controlled R	oom – betwe	en 20 and 25	C (68° – 77° f	
DUNS:	968961354							Other Te	emperature Range Re	quirement					
Proprietary Name (If Applical	ble) and Established N	Name: Fondapari	inux Sodium Injection, USP 7.5 mg p	er 0.6 mL (10's)					rite in)	•					
Selling Unit NDC:	55150-232-10		Individual Unit NDC:	55150-232-00	UPC	3551502321	109								
UDI			CVX Code:		MVX Code:			Is this pr	oduct to be shipped to	o customers o	on ice?				
Description:	Fondaparinux Sodium	Injection, USP 7.5 mg pe	r 0.6 mL (10's)					Is this pr	oduct to be shipped to	o customers o	on dry ice?				
A - 11 I 11 11->		T													
Active Ingredient(s):								b. Contact for tempera Name:	ture excursion ques	tions:					
URL for Additional Product II	nformation:	www.auromedics.com						Number	:						
Address:	279 Princeton-Hightsto	own Road			Address 2:			Group E	-mail:						
City:	East Windsor			State:	NJ	Zip:	08520								
Key Contact:				Email: Fax:				c. Special regulations					No	•	
Phone Number:	888-238-7880			rax:	732-355-9449			Special	returns requirements	for this produ	ct?		No	•	
Product Therapeutic Classifi	cation:							d. Store product (unit of	of cale) upright?				Yes		
ADDITIONA	L PRODUCT INFORM.	ATION	ı	Р	RODUCT DESCR	RIPTION INFORM	MATION		product (unit of sale) from light?			No	•	
Is the Product		-	ſ					e. Shelf life:		, .			24	Months	
a legend device?		No							nelf life at launch (if	different):			27	Months	
reverse numbered?		No		Size:	1 PFS I	Jnit			(,-					
co-licensed?		No		Strength:	7.5 mg	per 0.6 mL			0	RDER INFOR	RMATION				
Is the Product		Direct-Ship Only		-											
Is the Product				Dosage Form:	LIQUID			Unit of S	Bottle		What is the 55150-232-1			ringes	
								x	Box/Carton		(Write-in, e.g			iiigoo	
If Unit Dose, is item bar code		tal scanning?		Product Shape:					Ampule			=			
If Unit Dose NDC, indicate NI	DC here:			. rounds onup		re filled syringe)		Glass Minimum order quantity?							
Country of Origin	Country of Origin India							Tube Vial Liquid Sgl							
						Vial Liquid Multi		If Yes, how	many of wh	ich package	type?				
Is this product covered under the Trade Agreements Act (TAA)? No Product Imprint:							Vial Powder Sql		1	Each					
			J						Vial Power Multi			Inner/Carton	/Pack		
			FOR GENERIC DRUG PRODUCTS						Other: Write In	1	80	Case			
			TOR SENERIO DIROCT RODOGTO												
				Autho	rized Generic	*If Authorized	d Generic, other section		PHAR	MACY ORDE	R / BILL UNI	Т			
I. Orange Book Rating:	AP					fields are not	t applicable	Rec. sell unit to custor	mer?		Rx billing unit to pharmacy:				
II. Generic Equivalent to Wha	at Brand?:	Arixtra Injection						Each							
		DRIIC SUBBLY	CHAIN SECURITY ACT (DSCSA)	NEORMATION				(Write-in, e.g. 1 Vial)				Gram Milliliter			
		DRUG SUFFEI	CHAIN SECONT FACT (BSCSA)	INI ORMATION								williller			
Does supplier meet DSCSA of	definition of manufacti			GLN:	0355150000005	5			ITEM AN	ND PACKING	INFORMATI	ON			
Is product exempt from DSC	SA?	N	No												
If yes, select exemption: Other exemption - Write in:	İ						ī		Weight Lbs.	Dimer Depth	nsions (US m Height	smts.) Width	Volume (Cube)	# Pieces:	
Is product repackaged?	ļ	N	No	If Yes, was origina	al product purch	ased direct		Item:		Deptili	neight	wium			
Is product sold by manufactu	urer's exclusive distrib	outor?		from mfr?									0		
Has FDA granted waiver/exce	eption/exemption for p	product?	No	If yes, attach docu	mentation from	FDA.		Box/Carton/Bundle/	5.0926	14.41	7.48	8.9	959.30252	one E-Flute b	
			GTIN PRODUCT INFORMATION					Inner Pack: Case:							
			Saleable					Case:	6.536	15.551	9.055	9.843	1386.0352	box, 1 E-Flute	
			Level Unit			Quantity	GTIN-14	Pallet:	Sea: 346.775	48	Sea: 41.22	40	#VALUE!	3EA. 10 PFS in	
Serialized?		. —	Item X	2D	Linear	10	10355150232106		Air: 425.212		Air: 50.28	40	#VALUE!	Carton 8	
If not, when?			Box/Carton/Bundle/Inner Pack	2D	Linear	80	30355150232100	UPC:	Case:	5035515023					
Items aggregated?			Case Pallet	2D 2D	Linear	80 4800	50355150232104 70355150232108		Carton:	1035515023	32106				
		×	unus	2D 2D	Linear	4000	. 5555 155252 100	COST	INFORMATION			WHOLESAL	ER USE ONL	.Y:	
				2D	Linear										
				2D	Linear			Regular Cost			Vendor #:				
				2D	Linear			Invoice Cost (WAC) (\$)		\$580.00	Whsl. Code				
								Federal Excise Tax Pe As of date:	r Unit of Sale 1/17/2018	1	Fineline Cod	ie:			
								, is of date.	., 11/2010		t				
		At	ttach copy of SAFETY DATA SHEET	(SDS) or non haza	rd letter, PACKA	GE INSERT, LAB	BEL AND PHOTO OF PRO	DUCT PACKAGING and B	ARCODE.						
*Please provide any addition	al information on page		•		See new p. 3 fo			Signatu							





Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI	Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax Fax Number: c. Fax d. Phone only e. Supplier Web Site only Fax Number: Fax Num	Shipping lead time of PO: Hours Days Ships same day for next day receipt:
Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	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:
Drop Ship service fee billed with each order:	PO Receipt cut off time:
Drop Ship miscellaneous fees billed: Comments:	Days of week overnight is available: Monday 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 physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
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?



					Introduction	n Type:	New Item		Final Version			Date:		
			PRODUCT INFORMATION						SPECIAL HANDLI	ING AND STO	RAGE REQU	JIREMENTS	*	
Company Name:	AuroMedics Pharma L	LC			A	pplication:	ANDA	a. Temperature – Indic	ate the USP tempera	ature range fo	or this produ	ct.		
Application Number for ND	A/ANDA/BLA (drug); F	PMA/510(k)(med device):		0206918				Tempera	ature Range		Controlled R	oom – betwe	en 20 and 25	C (68° – 77° I
DUNS:	968961354							Other Te	emperature Range Re	quirement				
Proprietary Name (If Applica	ble) and Established N	Name: Fondapari	inux Sodium Injection, USP 10 mg pe	er 0.8 mL (10's)					rite in)					
Selling Unit NDC:	55150-233-10		Individual Unit NDC:	55150-233-00	UPC	'3551502331	06							
UDI			CVX Code:		MVX Code:			Is this pr	roduct to be shipped to	o customers o	on ice?			
Description:	Fondaparinux Sodium	Injection, USP 10 mg per	0.8 mL (10's)					Is this pr	roduct to be shipped to	o customers o	on dry ice?			
Active Ingredient(s):								b. Contact for tempera	tura avauraian auac	tions				
Active ingredient(s).								Name:	iture excursion ques	itions.				
URL for Additional Product I	nformation:	www.auromedics.com						Number	:					
Address:	279 Princeton-Hightst	own Road			Address 2:			Group E	-mail:					
City:	East Windsor			State:	NJ	Zip:	08520							
Key Contact:	888-238-7880			Email: Fax:	732-355-9449			c. Special regulations			0		No	-
Phone Number: Product Therapeutic Classifi				rax.	732-355-9449			Special	returns requirements	tor this produc	Ct?		No	-
Froduct Therapeutic Classiii	ication.							d. Store product (unit of	of sale) unright?				Yes	
ADDITIONA	AL PRODUCT INFORM	ATION		P	RODUCT DESCR	RIPTION INFORM	MATION		product (unit of sale) from light?			No	-
Is the Product								e. Shelf life:	. ,	,			24	Months
a legend device?		No		•	. 550				helf life at launch (if	different):				Months
reverse numbered?		No		Size:	1 PFS l	Jnit			,					•
co-licensed?		No		Strength:	10 mg r	per 0.8 mL			0	RDER INFOF	RMATION			
Is the Product		Direct-Ship Only		g										
Is the Product				Dosage Form:	LIQUID			Unit of S	Bottle		What is the		unit? O pre-filled syr	ringos
								x	Box/Carton		(Write-in, e.g			illiges
If Unit Dose, is item bar code	ed to unit dose for hospi	tal scanning?		Product Shape	DES (D	re filled syringe)			Ampule		,,	,	,	
If Unit Dose NDC, indicate N	DC here:			1 Todact Onape		ie illieu symige)		Glass Minimum order quantity?						
Country of Origin	Product Color:							Tube Vial Liquid Sgl						
Country of Origin India							Vial Liquid Sgi Vial Liquid Multi		If Yes. how	many of wh	ich package t	type?		
Is this product covered under the Trade Agreements Act (TAA)? No Product Imprint:							Vial Powder Sql		1	Each				
			L						Vial Power Multi			Inner/Carton	/Pack	
			FOR GENERIC DRUG PRODUCTS						Other: Write In	7	80	Case		
										1				
				Autho	rized Generic		d Generic, other section		PHAR	MACY ORDE	R / BILL UNI	Т		
I. Orange Book Rating:	AP					fields are not	t applicable	Rec. sell unit to custor	mer?	_	Rx billing ur	nit to pharm	асу:	
II. Generic Equivalent to Wha	at Brand?:	Arixtra Injection										Each		
		DRUG SUPPLY	CHAIN SECURITY ACT (DSCSA) I	NEORMATION				(Write-in, e.g. 1 Vial)				Gram Milliliter		
		5.100 001 1 2 1										Willinger		
Does supplier meet DSCSA				GLN:	0355150000005	5			ITEM AN	ND PACKING	INFORMATI	ON		
Is product exempt from DSC	SA?		lo .							Dimen	-i (IIC			
If yes, select exemption: Other exemption - Write in:							Ī		Weight Lbs.	Depth	nsions (US m Height	Width	Volume (Cube)	# Pieces:
Is product repackaged?		N	lo .	If Yes, was origina	al product purcha	ased direct		Item:		Бериі	rieigiit	widui		
Is product sold by manufactu	urer's exclusive distrib	outor?	No	from mfr?									0	
Has FDA granted waiver/exc	eption/exemption for p	product?	No	If yes, attach docu	mentation from	FDA.		Box/Carton/Bundle/	5.0926	14.41	7.48	8.9	959.30252	one E-Flute b
			GTIN PRODUCT INFORMATION					Inner Pack: Case:						
			Saleable					J J J J J J J J J J J J J J J J J J J	6.536	15.551	9.055	9.843	1386.0352	box, 1 E-Flute
			Level Unit			Quantity	GTIN-14	Pallet:	Sea: 346.775	48	Sea: 41.22	40	#VALUE!	3EA. 10 PFS in
Serialized?			Item X	2D	Linear	10	10355150233103		Air: 425.212		Air: 50.28		# V/\LOL:	Carton 8
If not, when?			Box/Carton/Bundle/Inner Pack Case	2D 2D	Linear	80	30355150233107	UPC:	Case:	5035515023				
Items aggregated?			Case Pallet	2D 2D	Linear	80 4800	50355150233101 70355150233105		Carton:	1035515023	33103			
		├		2D 2D	Linear	4000		COST	INFORMATION			WHOLESAL	ER USE ONL	LY:
				2D	Linear									
				2D	Linear			Regular Cost			Vendor #:			
				2D	Linear			Invoice Cost (WAC) (\$)		\$581.00	Whsl. Code			
								Federal Excise Tax Pe As of date:	1/17/2018		Fineline Cod	ie:		
								AS OF GARE:	1/11/2010					
											Ī			
		At	ttach copy of SAFETY DATA SHEET	(SDS) or non haza	rd letter, PACKA0	GE INSERT. LAB	BEL AND PHOTO OF PRO	DDUCT PACKAGING and B	BARCODE.					





Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI	Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax Fax Number: c. Fax d. Phone only e. Supplier Web Site only Fax Number: Fax Num	Shipping lead time of PO: Hours Days Ships same day for next day receipt:
Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	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:
Drop Ship service fee billed with each order:	PO Receipt cut off time:
Drop Ship miscellaneous fees billed: Comments:	Days of week overnight is available: Monday 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 physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
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?