

Version 2021	rsion 2021				Introduction	Introduction Type: New Item			Final Version			Date:	03.07	.2023	
	PRODUCT INFORMATION							SPECIAL HANDLING AND STOR			AGE REQUIREMENTS*				
Company Name:	Eugia US LLC (f/k	k/a AuroMedics Pha	Irma LLC)			Applica	Application: ANDA			a. Temperature – Indicate the USP temperature range for this product.					
Application Number for NDA/AN	DA/BLA (drug); P	MA/510(k)(med de	vice):	21	6379				Tem	perature Range	Controlled Room	– between 20	and 25 C (68	3° – 77° F)	
Medical Device Class, if applicable:															
DUNS:	968961354								Othe	r Temperature Range I	Requirement			excursions p	
Proprietary Name (If Applicable) a		ame:								(write in)		between 15°	to 30°C (59°	° to 86°F) [see	e USP
Selling Unit NDC:	55150-0429-01		Unit of Use NDC:		55150-0429-0	1 UPC: MVX Code:	355150	0429011	Note	S					
UDI		CVX Code:													
Description:	n: Tirofiban Hydrochloride Injection, 5 mg/100 mL (50 mcg/mL) (Mono pack)									s product to be shipped				No	
Active Ingredient(s): Is this product to be shipped to customers on dry ice? No															
Active ingredient(s): Infoldan Hydrochlonde b. Contact for temperature excursion questions:															
URL for Additional Product Inform	nation:	eugiaus.com							Nam		conoria.	Kevin Cagne	etti		
Address:	279 Princeton-Hig	Princeton-Hightstown Road			Address 2:			Num	ber:		732.839.940	0 ex 8009			
City:	East Windsor				State:	NJ	Zip:	08520	Gro	up E-mail:		kcagnetti@	EugiaUS.c	:om	
Key Contact:					Email:										
Phone Number:	888-238-7880				Fax:	732-355-9449			c. Special regulations for product in any states? No						
Product Therapeutic Classificatio	n:	Platelet Aggregat	ion Inhibitor/Antiplatelet Agent	S					Spe	cial returns requirement	ts for this product?			No	
		ONAL PRODUCT I				PRODUCT	DESCRU	PTION INFORMATION	d Store product (	nit of sale) upright?				No	
The use during in C	ADDITIO	SNALT KODUCT II		Direct Oh	Only		DEGCKI								
The product is? a legend device?		No	Is the Product Is the Product	Direct-Ship Neither	Unity		ſ	100 mL Single-Dose Cont	Prot e. Shelf life:	ect product (unit of s	ale) from light?			No 24	Months
a legend device? if yes, enter class #			Orphan Drug Status	INCIUICI		Size:	Too me single-bose con			al shelf life at launch (	if different).			24	Months
a product kit?		No	orphan brug olatao			<b>a</b>		5 mg per 100 mL (50 mcg							literitie
if yes, list NDCs of			FDA Approval Status			Strength:		510 00 00	-		ORDER INFORM	IATION			
component parts						Dosage For	m·	Liquid							
reverse numbered?		No				Decagoren			Unit	of Sale		What is the		unit?	
co-licensed?		No	Allergens Present				r			Bottle		1 box of 1 ba			
latex-free? preservative-free?		Yes Yes				Product Sha	ape:		<u> </u>	Box/Carton Ampule		(Write-in, e.	g. 1 Box of 1	0 Vials)	
correctional institution block?		No								Glass		Minimum o	rder quantity	2	Yes
opioid?		No				Product Col	lor:			Tube		Minimum of		,.	103
Cannabinoid?		No	Country of Origin	India		Product Imp	arint.			Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	init dose for					Froduct init	June.			Vial Liquid Multi				ich package	type?
hospital scanning?			Is this product covered u							Vial Powder Sql			Each		
If Unit Dose, indicate NDC here: Trade Agreements Act (TAA)? No								Vial Power Multi			Inner/Carton	/Pack			
							Other: Write In		1	Case					
FOR GENERIC DRUG PRODUCTS						_									
					Au	thorized Generic	*If Auth	horized Generic, other		PH.	PHARMACY ORDER / BILL UNIT				
I. Orange Book Rating: AP							Rec. sell unit to cu			Rx billing u	nit to pharm	acv:			
II. Generic Equivalent to What Brand?: AGGRASTAT® (tirofiban hydrochloride) injection								bag	1		Each	acy.			
							(Write-in, e.g. 1 Via		-1		Gram				
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION															
				_											
Does supplier meet DSCSA defini	tion of manufactu	irer?	Yes	_	GLN:					ITEM	AND PACKING IN	FORMATION	N		
Is product exempt from DSCSA?			INU				_								
If yes, select exemption:					GCP:					Weight Lbs.		ons (US msm		Volume	Saleable # Pieces
Other exemption - Write in: Is product repackaged?			No		If yes was a	riginal product			Item/Each:		Depth	Width	Height	(Cube)	
Is product sold by manufacturer's	exclusive distrib	utor?	No	_		irect from mfr?			item/Lacii.	0.4183	10.039	6.692	1.771	118.978	1 bag
Has FDA granted waiver/exception				-		ce manufacturer f	or repac	ckaged product	Box/Carton/Bundle	/					
If yes, attach documentation from	m FDA.								Inner Pack:						
									Case:	5.9	14.566	10.236	11.417	1702.247	10 bags
		GT	IN AND HIBCC PRODUCT IN	IFORMATION					D-II-1						
Saleable Unit of Measure	c	Saleable Quantity	HIBCC		GTI	N-14		Unit of Use GTIN-14	Pallet:	292.64	48	40	50.66	97267.20	440 bags
x Item/Each		1	TIBOO			55150429011		00355150429011							
Box/Carton/Bundle/Inner Pack									COST INFORMATION WHOLESALER USE ONLY:						
Case 10 50355150429016															
Pallet	Pallet 440 70355					55150429010			Regular Cost			Vendor #:			
							Invoice Cost (WAC	) (\$)	\$87.40	Whsl. Code					
	-				-		-		As of date:	7/6/2023		Fineline Co	ue:		
	-				-				AS OF DALE.	1/0/2020					
	1														
			Attach copy of SAFETY DA	TA SHEET (SD	S) or non hazar	d letter, PACKAGE	INSERT	T, LABEL AND PHOTO OF F	PRODUCT PACKAGIN	G and BARCODE.		•			
*Please provide any additional inf	ormation on page	2.			,			nated Drop Ship Only.		ature:		[	D.Venkata Su	render Redd	y
-						-									

Version 2021 For Designat	ted Drop Ship Only Products, Please Use Page 3
MATERIAL HA	ZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply): a. Cytotoxic? No 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? No Does the product label bear a CA Prop 65 warning? No	SDS Hazard Classification       Organic     Corrosive       Inorganic     Oxidizer       Steroid/Androgen     Contact Hazard
c. Contact Hazard?     No       d. Does this product require special clean-up instructions?     No       (If yes, attach SDS with special instructions.)     No       e. Does the product contain DEHP?     No       Is this product regulated for shipment by DOT?     No       (if yes, answer a-e below and provide SDS)     a.       a. UN/Identification Number     UN/Identification Number	Does the product have an Aerosol class? If yes, identify NFPA Storage Level:       No         NFPA Storage Level:       Image: Storage Level:         Is the product a NIOSH hazardous drug?       No         If yes, indicate which:       Image: Storage Level:
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? No	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics
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 d. Packing Group a. Instantian Uncertainty of the second	REMS or REGISTRY RESTRICTIONS         Is there a REMS on this product?       No         If Yes, is it managed with a pharmacy registry?       Website URL:
e. Inhalation Hazard? No Is the product restricted for air shipment? If so, indicate restriction: No Passenger Cargo Passenger & Cargo La blace searchable	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)
Is this a reportable quantity? No RQ Threshold: Is this a marine pollutant? No Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below) Limited Quantity Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4) Special Permit; DOT-SP Special Perovision (listed in Column 7 of 49 CFR 172.101);	REMS:     No       REMS Program Manager Name:     Phone:       Supplier Manages REMS registry exclusively:     Phone:       Wholesale distributor support:     Provider Name:       Provider Name:     DEA #:       Site Enrollment Number assigned     NCPDP#:       by Supplier:     NPI #:
SP#	Registry: No
ADD'L STORAGE INFORMATION Is the Product	Registry Program Contact Name:     Phone:       Comments
Controlled Substance?         No         Controlled Substance Code           Controlled by State(s)?         No         Listed Chemical (List I or II)         No           ARCOS Reportable?         No         If yes, indicate which:         If yes, indicate chemical product?:         No	RETURN INSTRUCTIONS         Contact tel. # if product received damaged:         Is product returnable for credit:         Yes
CLASS OF TRADE RESTRICTION: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	URL/Link to returns policy: https://eugiaus.com/policies/return-policy/
Restricted to retail pharmacy only:       No         Restricted to hospital, clinics, and physician offices only:       No         Restricted from US territories? (explain in comments)       No         Comments:	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?
MISCELLANE	OUS NOTES and/or Image of Product Barcode:



Version 2021 FOR DESIGN/	TED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.
Order Method 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 Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	ber:     Shipping lead time of PO:     Hours     Days       o.:
Expedited Freight Charges or Other Designation	ted Drop Ship Fees: Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order: 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
	Priority Overnight receipt available:
Class of Trade Restrictio No restriction: Select YES if sold to retail pharmacy, hospitals, clini Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	
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?



Version 2021						Introduction T	ype:	New Item		Final Version			Date:	03.07	.2023
	PRODUCT INFORMATION					SPECIAL HANDLING AND STOR			AGE REQUIR	REMENTS*					
Company Name:					Applicat	ion:	ANDA	a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 216379 Temperature Range Controlled Room - between 20 and 25 C (68° - 77°							3° – 77° F)								
Medical Device Class, if applicable:															
DUNS:	968961354									Temperature Range I	Requirement			excursions p	
Proprietary Name (If Applicable) a		Name:	Unit of Use NDC:		55450 0400 0					write in)		between 15°	to 30°C (59°	° to 86°F) [see	e USP
Selling Unit NDC: UDI	55150-0430-01		CVX Code:		55150-0430-0	1 UPC: MVX Code:	3551504	30017	Notes						
Description: Tirofiban Hydrochloride Injection, 12.5 mg/250 mL (50 mcg/mL) (Mono pack) Is this product to be shipped to customers on dry ice? No															
Active Ingredient(s): Tirofiban Hydrochloride Is this product to be shipped to customers on dry ice? No															
b. Contact for temperature excursion questions:															
URL for Additional Product Inform		eugiaus.com							Name	:		Kevin Cagne			
Address:	279 Princeton-Hightstown Road			Address 2:			Numb			732.839.940					
City: Key Contact:	East Windsor				State: Email:	NJ	Zip:	08520	Group E-mail: kcagnetti@EugiaUS.com						
Phone Number:	888-238-7880				Fax:	732-355-9449			c. Special regulation	s for product in any	states?			No	
Product Therapeutic Classificatio		Platelet Aggregatio	n Inhibitor/Antiplatelet Agent	s		102 000 0110				al returns requirement				No	
		r lateret riggregatio	in ministerit, and plateret rigeri						opeon					110	
	ADDIT	IONAL PRODUCT IN	FORMATION			PRODUCT	DESCRIPT	TION INFORMATION	d. Store product (un	t of sale) upright?				No	
The product is?			Is the Product	Direct-Ship	Only				Prote	t product (unit of s	ale) from light?			No	
a legend device?		No	Is the Product	Neither		Size:	25	50 mL Single-Dose Cont	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status			OILC.			Initial	shelf life at launch (	if different):				Months
a product kit?		No	FD4 4			Strength:	12	2.5 mg per 250 mL (50 m			ORDER INFORM				
if yes, list NDCs of component parts			FDA Approval Status					iquid			ORDER INFORM	IATION			
reverse numbered?		No				Dosage Form	n: "	iquiu	Unit o	f Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present							Bottle		1 box of 1 ba			
latex-free?		Yes				Product Sha	no:		x	Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		Yes				i roduct ona	pe			Ampule					
correctional institution block?		No				Product Cold	or:			Glass		Minimum o	der quantit	y?	Yes
opioid? Cannabinoid?		No	Country of Origin	India						Tube Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	init dose for	No	Country of Origin	Inula		Product Imp	rint:			Vial Liquid Sgl		If Yes, how	many of wh	ich nackade	type?
hospital scanning?			Is this product covered u	nder the						Vial Powder Sol			Each	ich package	type:
If Unit Dose, indicate NDC here:			Trade Agreements Act (		No					Vial Power Multi			Inner/Cartor	/Pack	
								Other: Write In		1	Case				
			FOR GENERIC DRUG PRO	ODUCTS											
Authorized Generic, other     *If Authorized Generic, other       I. Orange Book Rating:     AP															
I. Orange Book Rating: AP II. Generic Equivalent to What Brand?: AGGRASTAT® (tirofiban hydrochloride) injection					00000111	iolae ale net applicable	Rec. sell unit to cust		1		Each	acy:			
							(Write-in, e.g. 1 Vial)	ag	_		Gram				
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION															
Does supplier meet DSCSA defini	ition of manufact	urer?	Yes	_	GLN:				ITEM AND PACKING INFORMATION						
Is product exempt from DSCSA?			.10		000						Dim'	ama /110 m	14 N	Malan	0-1
If yes, select exemption: Other exemption - Write in:					GCP:					Weight Lbs.	Dimension	ons (US msm Width		Volume (Cube)	Saleable # Pieces
Is product repackaged?			No		If ves, was or	iginal product			Item/Each:				Height		
Is product sold by manufacturer's	s exclusive distrib	butor?	No	-		rect from mfr?				0.7815	11.614	7.086	1.771	145.748	1 bag
Has FDA granted waiver/exceptio	n/exemption for					ce manufacturer fo	or repack	aged product	Box/Carton/Bundle/						
If yes, attach documentation from	m FDA.								Inner Pack:						
		GTIN	AND HIBCC PRODUCT IN						Case:	9.555	15.354	10.236	12.992	2041.869	10 bags
		GIII		FORMATION					Pallet:						
Saleable Unit of Measure		Saleable Quantity	HIBCC		GTI	N-14	1	Unit of Use GTIN-14	. anot.	415.24	48	40	56.97	109382.40	400 bags
X Item/Each		1				55150430017		00355150430017							
Box/Carton/Bundle/Inner Pack	Box/Carton/Bundie/Inner Pack								CC	ST INFORMATION		١	WHOLESAL	ER USE ONL	.Y:
Case		10				55150430012			December C. 1						
Pallet	T	400			703	55150430016	-		Regular Cost			Vendor #:			
							Invoice Cost (WAC) (\$) \$227.05				Whsl. Code #: Fineline Code:				
							†		As of date:	7/6/2023					
	İ						1								
							_								
			Attach copy of SAFETY DA	TA SHEET (SD	S) or non hazar										
*Please provide any additional inf	formation on pag	e 2.				See new p. 3 for	Designat	ted Drop Ship Only.	Signa	ture:		[	0.Venkata Su	render Reddy	y

Version 2021 For Designat	ted Drop Ship Only Products, Please Use Page 3
MATERIAL HA	ZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply): a. Cytotoxic? No 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? No Does the product label bear a CA Prop 65 warning? No	SDS Hazard Classification       Organic     Corrosive       Inorganic     Oxidizer       Steroid/Androgen     Contact Hazard
C. Contact Hazard?     No     C. Contact Hazard?     No     (If yes, attach SDS with special instructions?     (If yes, attach SDS with special instructions.)     e. Does the product contain DEHP?     No     Is this product regulated for shipment by DOT?     (if yes, answer a-e below and provide SDS)     a. UN/Identification Number     Definition	Does the product have an Aerosol class? If yes, identify NFPA Storage Level:       No         NFPA Storage Level:       Image: Storage Level:         Is the product a NIOSH hazardous drug?       No         If yes, indicate which:       Image: Storage Level:
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? No	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics
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 d. Packing Group a. Instantian Uncertainty of the second	REMS or REGISTRY RESTRICTIONS         Is there a REMS on this product?       No         If Yes, is it managed with a pharmacy registry?       Website URL:
e. Inhalation Hazard? No Is the product restricted for air shipment? If so, indicate restriction: No Passenger Cargo Passenger & Cargo La blace searchable	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)
Is this a reportable quantity? No RQ Threshold: Is this a marine pollutant? No Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below) Limited Quantity Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4) Special Permit; DOT-SP Special Perovision (listed in Column 7 of 49 CFR 172.101);	REMS:     No       REMS Program Manager Name:     Phone:       Supplier Manages REMS registry exclusively:     Phone:       Wholesale distributor support:     Provider Name:       Provider Name:     DEA #:       Site Enrollment Number assigned     NCPDP#:       by Supplier:     NPI #:
SP#	Registry: No
ADD'L STORAGE INFORMATION Is the Product	Registry Program Contact Name:     Phone:       Comments
Controlled Substance?         No         Controlled Substance Code           Controlled by State(s)?         No         Listed Chemical (List I or II)         No           ARCOS Reportable?         No         If yes, indicate which:         If yes, indicate chemical product?:         No	RETURN INSTRUCTIONS         Contact tel. # if product received damaged:         Is product returnable for credit:         Yes
CLASS OF TRADE RESTRICTION: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	URL/Link to returns policy: https://eugiaus.com/policies/return-policy/
Restricted to retail pharmacy only:       No         Restricted to hospital, clinics, and physician offices only:       No         Restricted from US territories? (explain in comments)       No         Comments:	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?
MISCELLANE	OUS NOTES and/or Image of Product Barcode:



Version 2021 FOR DESIGN/	TED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.
Order Method 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 Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	ber:     Shipping lead time of PO:     Hours     Days       o.:
Expedited Freight Charges or Other Designation	ted Drop Ship Fees: Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order: 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
	Priority Overnight receipt available:
Class of Trade Restrictio No restriction: Select YES if sold to retail pharmacy, hospitals, clini Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	
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?