Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: New Item | [ ] Final Version | **Date:** 20.01.2018

PRODUCT INFORMATION

Company Name:	AuroMedics Pharma LLC			**Application:**	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	205962				
DUNS:	968961354				
Proprietary Name (If Applicable) and Established Name:	BIVALIRUDIN FOR INJECTION 250mg/Vial				
Selling Unit NDC:	55150-210-10	**Individual Unit NDC:**	55150-210-10	**UPC:**	'355150210107
UDI		**CVX Code:**		**MVX Code:**	
Description:	BIVALIRUDIN FOR INJECTION 250mg/Vial				
Active Ingredient(s):					
URL for Additional Product Information:	www.auromedics.com				
Address:	279 Princeton-Hightstown Road		**Address 2:**		
City:	East Windsor	**State:**	NJ	**Zip:**	08520
Key Contact:		**Email:**			
Phone Number:	888-238-7880	**Fax:**	732-355-9449		
Product Therapeutic Classification:	Anticoagulant				

ADDITIONAL PRODUCT INFORMATION

Is the Product…	
a legend device?	No
reverse numbered?	No
co-licensed?	No
Is the Product…	Direct-Ship Only
Is the Product…	
If Unit Dose, is item bar coded to unit dose for hospital scanning?	
If Unit Dose NDC, indicate NDC here:	
Country of Origin	India
Is this product covered under the Trade Agreements Act (TAA)?	No

PRODUCT DESCRIPTION INFORMATION

Size:	10 x 10 mL Single Dose Vials
Strength:	250mg/Vial
Dosage Form:	Lyophilized Powder
Product Shape:	Vial Pack
Product Color:	
Product Imprint:	

FOR GENERIC DRUG PRODUCTS

[ ] Authorized Generic *If Authorized Generic, other section fields are not applicable

I. Orange Book Rating: AP

II. Generic Equivalent to What Brand?: Angiomax

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?	Yes	**GLN:**	0355150000005
Is product exempt from DSCSA?	No		
If yes, select exemption:			
Other exemption - Write in:			
Is product repackaged?	No	**If Yes, was original product purchased direct from mfr?**	
Is product sold by manufacturer's exclusive distributor?	No		
Has FDA granted waiver/exception/exemption for product?	No	**If yes, attach documentation from FDA.**	

GTIN PRODUCT INFORMATION

		Level	Saleable Unit			Quantity	GTIN-14
Serialized?	x	Item	x		2D	10	10355150210104
If not, when?	x	Box/Carton/Bundle/Inner Pack			2D	60	30355150210108
Items aggregated?	x	Case			2D	240	50355150210102
	x	Pallet			2D	10800	70355150210106
					2D		
					2D		
					2D		
					2D		

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.

Temperature Range	Controlled Room – between 20 and 25 C (68° – 77° F
Other Temperature Range Requirement (write in)	Store at 20° to 25°C (68° to 77°F).
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No

b. Contact for temperature excursion questions:

Name:	Steve Lucas
Number:	888-238-7880
Group E-mail:	pvg@aurobindousa.com

c. Special regulations for product in any states?	No
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	Yes
Protect product (unit of sale) from light?	No
e. Shelf life:	24 Months
Initial shelf life at launch (if different):	Months

ORDER INFORMATION

Unit of Sale		**What is the NDC selling unit?**	
	Bottle	55150-210-10	
x	Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)	
	Ampule		
	Glass	**Minimum order quantity?**	
	Tube		
	Vial Liquid Sgl		
	Vial Liquid Multi	**If Yes, how many of which package type?**	
	Vial Powder Sql		Each
	Vial Power Multi	24	Inner/Carton/Pack
	Other: Write In		Case

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?

(Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy:

- Each
- Gram
- Milliliter

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Height	Width	Volume (Cube)	# Pieces:
Item:					0	
Box/Carton/Bundle/ Inner Pack:	2.598	13.82	2.99	5.75	237.60035	one E-Flute b
Case:	11.931	14.763	7.126	12.204	1283.87469	x, 4 E-Flute b
Pallet:	Sea: 569.945 Air: 784.707	48	Sea: 40.87 Air: 55.12	40	#VALUE!	SEA: 10 Vials in Carton, 6
UPC:	**Case:**	50355150210102				
	Carton:	10355150210104				

COST INFORMATION

Regular Cost	
Invoice Cost (WAC) ($)	$4,000.00
Federal Excise Tax Per Unit of Sale	
As of date:	

WHOLESALER USE ONLY:

Vendor #:	
Whsl. Code #:	
Fineline Code:	

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

***Please provide any additional information on page 2.**

See new p. 3 for Designated Drop Ship Only.

Signature:

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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD 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
c. Contact Hazard?	No
d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)	No
e. Does the product contain DEHP?	No
Is this product regulated for shipment by DOT or IATA? (if yes, answer a-e below and provide SDS)	No
a. UN/Identification Number	
b. Proper Shipping Name	
c. DOT Hazard Class	
d. Packing Group	
e. Inhalation Hazard?	

Is the product restricted for air shipment? If so, indicate restriction:

- ☐ Passenger
- ☐ Cargo
- ☐ Passenger & Cargo

Is this a reportable quantity?

RQ Threshold:

Is this a marine pollutant?

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 Provision (listed in Column 7 of 49 CFR 172.101);

SP#

SDS Hazard Classification

- ☐ Organic
- ☐ Inorganic
- ☐ Steroid/Androgen
- ☐ Corrosive
- ☐ Oxidizer
- ☐ Contact Hazard
- ☐ Aerosol Class; Identify NFPA Storage Level:

Is the product a NIOSH hazardous drug?

If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code:

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry?

Website URL:

Comments / Details: (For example, iPledge program?)

REMS:

REMS Program Manager Name: Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:

Site Enrollment Number assigned by Supplier:

DEA #:

PCPDP #:

NPI #:

Comments

Registry:

Registry Program Contact Name: Phone:

Comments

ADD'L STORAGE INFORMATION

Is the Product…

Controlled Substance?	No
Controlled by State(s)?	No
ARCOS Reportable?	No
Schedule No. (inc. N for non-narcotic)	
Controlled Substance Code	
Listed Chemical (List I or II)	No
If yes, indicate which:	
Is it a scheduled listed chemical product?:	No

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Yes
Restricted to retail pharmacy only:	
Restricted to hospital, clinics, and physician offices only:	
Restricted from US territories? (explain in comments)	

Comments:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 888-238-7880

Is product returnable for credit:

URL/Link to returns policy: http://auromedics.com/policies/return-policy/

Special regulations or returns requirements for this product in certain states?

If so, which states? Other requirements? Comments?

MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE

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FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product

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:
Supplier's Customer Service Number:
Contracted 3PL company / contact #: Name:
Phone:

Standard Order Receipt and Processing

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:

Expedited freight fees billed with each order:
Drop Ship service fee billed with each order:
Drop Ship miscellaneous fees billed:
Comments:

Overnight and Priority Overnight PO Processing

Overnight receipt available:
PO Receipt cut off time:
Days of week overnight is available:
- Monday
- Tuesday
- Wednesday
- Thursday
- Friday

Priority Overnight receipt available:
PO Receipt Cut off time:

Saturday Overnight receipt available:
PO Receipt Cut off time:

Order receipt method:
Phone: Phone #:
Fax: Fax #:
EDI:
Overnight Fees apply:
Other fees apply:

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:

Other Data Information Required to Process PO:

Patient Procedure Date:
Physician Name:
Physician/Clinic Phone #
Physician State License #
Physician/Clinic DEA #:
Physician/Clinic Specialty:

Return Instructions

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?