

Version 2024

Introduction Type: New Item

Final Version

Date: 08.11.2023

[illegible]



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

Version 2024

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?

No

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?

c. Contact Hazard?

Yes

d. Does this product require special clean-up instructions?

No

(If yes, attach SDS with special instructions.)

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. UN/Identification Number

b. Proper Shipping Name

c. DOT Hazard Class

d. Packing Group

e. Inhalation Hazard?

Is this product regulated for shipment by IATA?

No

(if yes, answer a-e below and provide SDS)

a. UN/Identification Number

b. Proper Shipping Name

c. DOT Hazard Class

d. Packing Group

e. Inhalation Hazard?

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

No

☐ Passenger

☐ Cargo

☐ Passenger & Cargo

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?

☐ No (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#

### ADD'L STORAGE INFORMATION

Is the Product...

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:

Schedule No.

Is it a scheduled listed chemical product?:

### CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices

Yes

Restricted to retail pharmacy only:

No

Restricted to hospital, clinics, and physician offices only:

No

Restricted from US territories? (explain in comments)

No

Comments:

### SDS Hazard Classification

☐ Organic

☐ Inorganic

☐ Steroid/Androgen

☐ Corrosive

☐ Oxidizer

☐ Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:

No

NFPA Storage Level:

Is the product a NIOSH hazardous drug?

No

If yes, indicate which:

### Hazardous Waste Identification

EPA Hazardous Waste Code:

Waste Characteristics

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

No

If Yes, is it managed with a pharmacy registry?

Website URL:

Med Guide Required

No

Limited Distribution Requirement

No

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

#### REMS:

REMS Program Manager Name:

Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:

DEA #:

Site Enrollment Number assigned

NCPDP#:

by Supplier:

NPI #:

Comments

#### Registry:

Registry Program Contact Name:

Phone:

Comments

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit:

Yes

URL/Link to returns policy:

<https://eugiaus.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



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

Version 2024

FOR DESIGNATED 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
<p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="text"/></p> <p>b. Autofax <input type="text"/></p> <p>c. Fax <input type="text"/></p> <p>d. Phone only <input type="text"/></p> <p>e. Supplier Web Site only <input type="text"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <input type="text"/></p>	<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="text"/></p> <p>Ships for second day receipt: <input type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="text"/></p>
<p><b>Expedited Freight Charges or Other Designated Drop Ship Fees:</b></p> <p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p><b>Overnight and Priority Overnight PO Processing</b></p> <p><b>Overnight receipt available:</b> <input type="text"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p><b>Priority Overnight receipt available:</b> <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: <input type="text"/></p> <p>Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="text"/></p> <p>Other fees apply: <input type="text"/></p>
<p><b>Class of Trade Restriction:</b></p> <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="text"/></p> <p>Restricted to retail pharmacy only: <input type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="text"/></p> <p>Restricted from US territories? (explain in comments) <input type="text"/></p> <p>Comments: <input type="text"/></p>	
<p><b>Other Data Information Required to Process PO:</b></p> <p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p><b>Return Instructions</b></p> <p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="text"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="text"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>
<p><b>Miscellaneous Notes:</b></p> <p><input type="text"/></p>	<p><b>ADDITIONAL INFORMATION</b></p> <p>Is product order for scheduled patient procedure? <input type="text"/></p> <p>Is product order for restocking purposes? <input type="text"/></p>



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

Version 2024

Introduction Type:  New Item Final VersionDate:  08.11.2023

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
<b>Company Name:</b> Eugia US LLC (f/k/a AuroMedics Pharma LLC)				<b>Application:</b> ANDA			
<b>Application Number for NDA/ANDA/BLA; PMA/510(k):</b>				<b>NDA 505(b) Type:</b>			
<b>Medical Device Class, if applicable:</b>							
<b>DUNS:</b> 968961354							
<b>Proprietary Name (If Applicable) and Established Name:</b>							
<b>Selling Unit NDC:</b> 55150-351-03				<b>Unit of Use NDC:</b> 55150-351-01		<b>UPC:</b> 355150351039	
<b>UDI</b>				<b>CVX Code:</b>		<b>MVX Code:</b>	
<b>Description:</b> Icatibant Injection 30mg per 3mL (10mg/mL) Single-Dose prefilled Syringe (3's)							
<b>Active Ingredient(s):</b> Icatibant							
<b>URL for Additional Product Information:</b> <a href="https://eugiaus.com/products/">https://eugiaus.com/products/</a>							
<b>Address:</b> 279 Princeton-Hightstown Road				<b>Address 2:</b>			
<b>City:</b> East Windsor				<b>State:</b> NJ		<b>Zip:</b> 08520	
<b>Key Contact:</b>				<b>Email:</b>			
<b>Phone Number:</b> 888-238-7880				<b>Fax:</b> 732-355-9449			
<b>Product Therapeutic Classification:</b> Hematological Agent							
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
<b>The product is?</b>		<b>Is the Product...</b>		<b>Size:</b>		<b>1 PFS</b>	
<b>a legend device?</b>		<b>Is the Product...</b>		<b>Strength:</b>		<b>30 mg per 3 mL (10 mg/mL)</b>	
<b>if yes, enter class #</b>		<b>Orphan Drug Status</b>		<b>Dosage Form:</b>		<b>Solution</b>	
<b>a product kit?</b>		<b>FDA Approval Status</b>		<b>Product Shape:</b>		<b>PFS</b>	
<b>if yes, list NDCs of component parts</b>		<b>Approved for Orphan Indication</b>		<b>Product Color:</b>		<b>Clear</b>	
<b>reverse numbered?</b>		<b>Allergens Present</b>		<b>Product Imprint:</b>			
<b>co-licensed?</b>							
<b>latex-free?</b>							
<b>preservative-free?</b>							
<b>correctional institution block?</b>							
<b>opioid?</b>							
<b>Cannabinoid?</b>							
<b>If Unit Dose, is item bar coded to unit dose for hospital scanning?</b>		<b>Country of Origin</b> India					
<b>If Unit Dose, indicate NDC here:</b> 55150-351-01		<b>Is this product covered under the Trade Agreements Act (TAA)?</b> No					
FOR GENERIC DRUG PRODUCTS							
<b>I. Orange Book Rating:</b> AP				<input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable			
<b>II. Generic Equivalent to What Brand?:</b> Firazyr							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
<b>Does supplier meet DSCSA definition of manufacturer?</b> Yes				<b>GLN:</b>			
<b>Is product exempt from DSCSA?</b> No				<b>GCP:</b>			
<b>If yes, select exemption:</b>				<b>If yes, was original product purchased direct from mfr?</b>			
<b>Other exemption - Write in:</b>				<b>Provide source manufacturer for repackaged product</b>			
<b>Is product repackaged?</b> No							
<b>Is product sold by manufacturer's exclusive distributor?</b> No							
<b>Has FDA granted waiver/exception/exemption for product?</b>							
<b>If yes, attach documentation from FDA.</b>							
GTIN AND HIBCC PRODUCT INFORMATION							
<b>Saleable Unit of Measure</b>		<b>RFID tag(Y/N)</b>	<b>Saleable Quantity</b>	<b>HIBCC</b>	<b>GTIN-14</b>	<b>Unit of Use GTIN-14</b>	
<input checked="" type="checkbox"/> Item/Each			3		00355150351039		
<input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack			12		30355150351030		
<input checked="" type="checkbox"/> Case			24		50355150351034		
<input checked="" type="checkbox"/> Pallet			1920		70355150351038		
ITEM AND PACKING INFORMATION							
	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces	
		Depth	Width	Height			
<b>Item/Each:</b>	0.331	4.53	1.97	7.48	66.752	3	
<b>Box/ Carton/ Bundle/ Inner Pack:</b>	1.551	8.7	5.16	8.31	373.053	12	
<b>Case:</b>	4.022	11.417	9.645	9.842	1083.771	24	
<b>Pallet:</b>	354.775	48	40	54.21	104083.2	1920	
COST INFORMATION							
<b>Regular Cost</b>				<b>WHOLESALE USE ONLY:</b>			
<b>Invoice Cost (WAC) (\$)</b>				<b>Vendor #:</b>			
				<b>Whsl. Code #:</b>			
<b>As of date:</b> 5/8/2025				<b>Fineline Code:</b>			

\*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 PRODUCT PACKAGING AND BARCODE.

See new p. 3 for Designated Drop Ship Only.

Signature:

D.Venkata Surender Reddy



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

Version 2024

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? ☐ Yes
- 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?  
(if yes, answer a-e below and provide SDS)

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard? ☐ No

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
- e. Inhalation Hazard? ☐ No

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

- ☐ Passenger
- ☐ Cargo
- ☐ Passenger & Cargo

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?

- ☐ No (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#

### ADD'L STORAGE INFORMATION

Is the Product...

- 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:
- Schedule No.  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

Restricted to retail pharmacy only:

Restricted to hospital, clinics, and physician offices only:

Restricted from US territories? (explain in comments)

Comments:

### SDS Hazard Classification

- ☐ Organic ☐ Corrosive
- ☐ Inorganic ☐ Oxidizer
- ☐ Steroid/Androgen ☐ Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:

NFPA Storage Level:

Is the product a NIOSH hazardous drug?  
If yes, indicate which:

### Hazardous Waste Identification

EPA Hazardous Waste Code:

Waste Characteristics

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

If Yes, is it managed with a pharmacy registry?

Website URL:

Med Guide Required

Limited Distribution Requirement

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

#### REMS:

REMS Program Manager Name:

Supplier Manages REMS registry exclusively: ☐

Wholesale distributor support: ☐

Provider Name:

Site Enrollment Number assigned by Supplier:

Comments

#### Registry:

Registry Program Contact Name:

Comments

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit: ☐ Yes

URL/Link to returns policy:

<https://eugiaus.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



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

Version 2024

FOR DESIGNATED 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
<p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="text"/></p> <p>b. Autofax <input type="text"/></p> <p>c. Fax <input type="text"/></p> <p>d. Phone only <input type="text"/></p> <p>e. Supplier Web Site only <input type="text"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <input type="text"/></p>	<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="text"/></p> <p>Ships for second day receipt: <input type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="text"/></p>
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<p><b>Other Data Information Required to Process PO:</b></p> <p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p><b>Return Instructions</b></p> <p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="text"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="text"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>
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