

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) No

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) No

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: 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?: 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: No

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

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: 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? No
 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: No
 Wholesale distributor support: No
 Provider Name: DEA #:

Site Enrollment Number assigned by Supplier: NCPDP#: 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? No

If so, which states? Other requirements? Comments?

MISCELLANEOUS NOTES and/or Image of Product Barcode:



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

Version 2024 Introduction Type: New Item Final Version Date: 08.11.2023

PRODUCT INFORMATION

Company Name: Eugia US LLC (f/k/a AuroMedics Pharma LLC) Application: ANDA
 Application Number for NDA/ANDA/BLA; PMA/510(k): NDA 505(b) Type:
 Medical Device Class, if applicable:
 DUNS: 968961354
 Proprietary Name (If Applicable) and Established Name:
 Selling Unit NDC: 55150-351-03 Unit of Use NDC: 55150-351-03 UPC: 355150351039
 UDI CVX Code: MVX Code:
 Description: Icatibant Injection 30mg per 3mL (10mg/mL) Single-Dose prefilled Syringe (3's)
 Active Ingredient(s): Icatibant
 URL for Additional Product Information: <https://eugiaus.com/products/>
 Address: 279 Princeton-Hightstown Road East Windsor NJ 08520
 City: East Windsor State: NJ Zip: 08520
 Key Contact: Email:
 Phone Number: 888-238-7880 Fax: 732-355-9449
 Product Therapeutic Classification: Hematological Agent

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 between 2° to 25°C (36° to 77°F). DO NOT FREEZE.
 Notes:
 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: Eugia US Customer Service
 Number: 888-238-7880
 Group E-mail: CustomerService@EugiaUS.com

c. Special regulations for product in any states?
 Special returns requirements for this product? No

d. Store product (unit of sale) upright? No
 Protect product (unit of sale) from light? Yes

e. Shelf life:
 Initial shelf life at launch (if different): 24 Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is? a legend device? <input type="checkbox"/> No	Is the Product... Is the Product... <input type="checkbox"/> Direct-Ship Only	Size:	1 PFS
if yes, enter class # a product kit? <input type="checkbox"/> No	Orphan Drug Status <input type="checkbox"/> Approved	Strength:	30 mg per 3 mL (10 mg/mL)
if yes, list NDCs of component parts reverse numbered? <input type="checkbox"/> No	FDA Approval Status <input type="checkbox"/> Approved for Orphan Indication	Dosage Form:	Solution
co-licensed? <input type="checkbox"/> No	Allergens Present	Product Shape:	PFS
latex-free? <input type="checkbox"/> Yes	Country of Origin <input type="text"/> India	Product Color:	Clear
preservative-free? <input type="checkbox"/> Yes		Product Imprint:	
correctional institution block? opioid? <input type="checkbox"/> No			
Cannabinoid? <input type="checkbox"/> No			
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/> Yes	Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No		
If Unit Dose, indicate NDC here: 55150-351-01			

ORDER INFORMATION

Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	55150-351-03
<input type="checkbox"/> Box/ Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity? <input type="checkbox"/> Yes
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	<input type="checkbox"/> Each
<input type="checkbox"/> Vial Power Multi	<input type="checkbox"/> Inner/ Carton/ Pack
<input type="checkbox"/> Other: Write In	<input type="text"/> 1 Case

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: AP Authorized Generic *If Authorized Generic, other section fields are not applicable
 II. Generic Equivalent to What Brand?: Firazyr

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer? 1 PFS
 (Write-in, e.g. 1 Vial)
 HCPCS J-Code:
 Rx billing unit to pharmacy:
 Each
 Gram
 Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

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

ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.331	4.53	1.97	7.48	66.752	3
Box/ Carton/ Bundle/ Inner Pack:	1.551	8.7	5.16	8.31	373.053	12
Case:	4.022	11.417	9.645	9.842	1083.771	24
Pallet:	354.775	48	40	54.21	104083.2	1920

GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<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	

COST INFORMATION

Regular Cost
 Invoice Cost (WAC) (\$) \$3,000.00
 As of date: 5/8/2025
WHOLESALE USE ONLY:
 Vendor #:
 Whsl. Code #:
 Fineline Code:



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

CLASS OF TRADE RESTRICTION:

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

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

Is the product a NIOSH hazardous drug? If yes, indicate which: No

Hazardous Waste Identification

EPA Hazardous Waste Code: Waste Characteristics:

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No Yes
If Yes, is it managed with a pharmacy registry? No Yes
Website URL:

Med Guide Required No Yes
Limited Distribution Requirement No Yes
Comments / Details: (For example, iPledge program?)

REMS: No Yes
REMS Program Manager Name: Phone:
Supplier Manages REMS registry exclusively: No Yes
Wholesale distributor support: No Yes
Provider Name: DEA #:
Site Enrollment Number assigned by Supplier: NCPDP#:
NPI #:

Comments

Registry: No Yes
Registry Program Contact Name: Phone:
Comments

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit: Yes No

URL/Link to returns policy: <https://eugiaus.com/policies/return-policy/>

Special regulations or returns requirements for this product in certain states? No Yes

If so, which states? Other requirements? Comments?

MISCELLANEOUS NOTES and/or Image of Product Barcode:

