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

Version 2021 | Introduction Type: Post Launch Change | Final Version | Date: 11/15/2022

PRODUCT INFORMATION

Company Name:	Eugia US LLC (f/k/a AuroMedics Pharma LLC)
Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	076092
Medical Device Class, if applicable:	
DUNS:	968961354
Proprietary Name (If Applicable) and Established Name:	Ketamine Hydrochloride Injection USP, 200 mg/20 mL (10 mg/mL) MDV
Selling Unit NDC:	55150-438-10
Unit of Use NDC:	55150-438-01
UPC:	355150438105
UDI	
CVX Code:	
MVX Code:	
Description:	Ketamine Hydrochloride Injection USP, 200 mg/20 mL (10 mg/mL) MDV
Active Ingredient(s):	Ketamine Hydrochloride
URL for Additional Product Information:	eugiaus.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:	

ADDITIONAL PRODUCT INFORMATION

The product is?	
a legend device?	No
if yes, enter class #	
a product kit?	No
if yes, list NDCs of component parts	
reverse numbered?	No
co-licensed?	No
latex-free?	Yes
preservative-free?	No
correctional institution block?	Yes
opioid?	No
Cannabinoid?	No
If Unit Dose, is item bar coded to unit dose for hospital scanning?	
If Unit Dose, indicate NDC here:	
Is the Product…	Direct-Ship Only
Is the Product…	Neither
Orphan Drug Status	
FDA Approval Status	
Allergens Present	
Country of Origin	Ireland
Is this product covered under the Trade Agreements Act (TAA)?	Yes

PRODUCT DESCRIPTION INFORMATION

Size:	10x20 mL
Strength:	200 mg/20 mL (10 mg/mL
Dosage Form:	Injection
Product Shape:	N/A
Product Color:	N/A
Product Imprint:	N/A

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?:	Ketalar

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	No
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?	No
If yes, attach documentation from FDA.	
GLN:	
GCP:	
If yes, was original product purchased direct from mfr?	
Provide source manufacturer for repackaged product	

GTIN AND HIBCC PRODUCT INFORMATION

	Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
x	Item/Each	10		00355150438105	
	Box/Carton/Bundle/Inner Pack				
	Case	60		50355150438100	
	Pallet	6300		70355150438104	

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). [See USP Controlled Room Temperature.]
Notes	Protect from light. Retain in carton until time of use.
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:	Kevin Cagnetti
Number:	732-839-9400 x8009
Group E-mail:	kcagnetti@EugiaUS.com

c. Special regulations for product in any states?	No
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:	36 Months
Initial shelf life at launch (if different):	Months

ORDER INFORMATION

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

PHARMACY ORDER / BILL UNIT

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

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Width	Height	Volume (Cube)	Saleable # Pieces
Item/Each:	1.247816	2.69685	2.854331	6.515748	50.15629	10
Box/Carton/Bundle/ Inner Pack:					0	
Case:	7.486896	8.66142	6.69291	5.62992	326.36705	60
Pallet:	786.12408	31.4961	47.24409	36.2205	53896.27	6300

COST INFORMATION

Regular Cost	
Invoice Cost (WAC) ($)	$193.03
As of date:	11/22/2022

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:

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

Version 2021

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?	
c. Contact Hazard?	No
d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)	Yes
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?	
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?	
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

- [x] Organic
- [ ] Inorganic
- [ ] Steroid/Androgen
- [ ] Corrosive
- [ ] Oxidizer
- [ ] 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?	No
If Yes, is it managed with a pharmacy registry?	
Website URL:	
Med Guide Required	
Limited Distribution Requirement	
Comments / Details: (For example, iPledge program?)	

REMS: No

REMS Program Manager Name:		Phone:	
Supplier Manages REMS registry exclusively:			
Wholesale distributor support:			
Provider Name:		DEA #:	
Site Enrollment Number assigned by Supplier:		NCPDP#:	
		NPI #:	

Comments

Registry:

Registry Program Contact Name:		Phone:	
Comments			

ADD'L STORAGE INFORMATION

Is the Product…

Controlled Substance?	Yes	Controlled Substance Code	7285
Controlled by State(s)?	No	Listed Chemical (List I or II)	No
ARCOS Reportable?	No	If yes, indicate which:	
Schedule No.	3N	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:	

RETURN INSTRUCTIONS

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

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

Version 2021

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:

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:

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:

Miscellaneous Notes:

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:

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:

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?

ADDITIONAL INFORMATION

Is product order for scheduled patient procedure?
Is product order for restocking purposes?

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

Version 2021 | Introduction Type: Post Launch Change | [ ] Final Version | Date: 11/15/2022

PRODUCT INFORMATION

Company Name:	Eugia US LLC (f/k/a AuroMedics Pharma LLC)
Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	076092
Medical Device Class, if applicable:	
DUNS:	968961354
Proprietary Name (If Applicable) and Established Name:	Ketamine Hydrochloride Injection USP, 500 mg/10 mL (50 mg/mL) MDV
Selling Unit NDC:	55150-439-10
Unit of Use NDC:	55150-439-01
UPC:	355150439102
UDI	
CVX Code:	
MVX Code:	
Description:	Ketamine Hydrochloride Injection USP, 500 mg/10 mL (50 mg/mL) MDV
Active Ingredient(s):	Ketamine Hydrochloride
URL for Additional Product Information:	eugiaus.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:	

ADDITIONAL PRODUCT INFORMATION

The product is?	
a legend device?	No
if yes, enter class #	
a product kit?	No
if yes, list NDCs of component parts	
reverse numbered?	No
co-licensed?	No
latex-free?	Yes
preservative-free?	No
correctional institution block?	Yes
opioid?	No
Cannabinoid?	No
If Unit Dose, is item bar coded to unit dose for hospital scanning?	
If Unit Dose, indicate NDC here:	
Is the Product…	Direct-Ship Only
Is the Product…	Neither
Orphan Drug Status	
FDA Approval Status	
Allergens Present	
Country of Origin	Ireland
Is this product covered under the Trade Agreements Act (TAA)?	Yes

PRODUCT DESCRIPTION INFORMATION

Size:	10x10 mL
Strength:	500 mg/10 mL (50 mg/mL
Dosage Form:	Injection
Product Shape:	N/A
Product Color:	N/A
Product Imprint:	N/A

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?:	Ketalar

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	No
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?	No
If yes, attach documentation from FDA.	
GLN:	
GCP:	
If yes, was original product purchased direct from mfr?	
Provide source manufacturer for repackaged product	

GTIN AND HIBCC PRODUCT INFORMATION

	Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
x	Item/Each	10		00355150439102	
	Box/Carton/Bundle/Inner Pack				
	Case	120		50355150439107	
	Pallet	10200		70355150439101	

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). [See USP Controlled Room Temperature.]
Notes	Protect from light. Retain in carton until time of use.
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:	Kevin Cagnetti
Number:	732-839-9400 x8009
Group E-mail:	kcagnetti@EugiaUS.com

c. Special regulations for product in any states?	No
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:	36 Months
Initial shelf life at launch (if different):	Months

ORDER INFORMATION

Unit of Sale	
	Bottle
X	Box/Carton
	Ampule
	Glass
	Tube
	Vial Liquid Sgl
	Vial Liquid Multi
	Vial Powder Sql
	Vial Power Multi
	Other: Write In

What is the NDC selling unit? 1 box of 10 vials (Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity? Yes

If Yes, how many of which package type?

	Each
	Inner/Carton/Pack
1	Case

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer? (Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy:

	Each
	Gram
x	Milliliter

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Width	Height	Volume (Cube)	Saleable # Pieces
Item/Each:	0.8730306	2.145669	2.73622	5.1377953	30.164111	10
Box/Carton/Bundle/ Inner Pack:					0	
Case:	10.4763672	12.9921	5.31496	5.62992	388.76	120
Pallet:	890.491212	31.4961	47.24409	35.4331	52724.615	10200

COST INFORMATION

Regular Cost	
Invoice Cost (WAC) ($)	$70.20
As of date:	11/22/2022

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:

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

Version 2021

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?	
c. Contact Hazard?	No
d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)	Yes
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?	
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?	
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

- [x] Organic
- [ ] Inorganic
- [ ] Steroid/Androgen
- [ ] Corrosive
- [ ] Oxidizer
- [ ] 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?	No
If Yes, is it managed with a pharmacy registry?	
Website URL:	
Med Guide Required	
Limited Distribution Requirement	
Comments / Details: (For example, iPledge program?)	

REMS: No

REMS Program Manager Name:		Phone:	
Supplier Manages REMS registry exclusively:			
Wholesale distributor support:			
Provider Name:		DEA #:	
Site Enrollment Number assigned by Supplier:		NCPDP#:	
		NPI #:	

Comments

Registry:

Registry Program Contact Name:		Phone:	
Comments			

ADD'L STORAGE INFORMATION

Is the Product…

Controlled Substance?	Yes	Controlled Substance Code	7285
Controlled by State(s)?	No	Listed Chemical (List I or II)	No
ARCOS Reportable?	No	If yes, indicate which:	
Schedule No.	3N	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:	

RETURN INSTRUCTIONS

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

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

Version 2021

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:

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:

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:

Miscellaneous Notes:

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:

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:

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?

ADDITIONAL INFORMATION

Is product order for scheduled patient procedure?
Is product order for restocking purposes?

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

Version 2024 | Introduction Type: Post Launch Change | Final Version | Date: 6/24/2026

PRODUCT INFORMATION

Company Name:	EUGIA US LLC			Application:	ANDA
Application Number for NDA/ANDA/BLA; PMA/510(k):	076092				
Medical Device Class, if applicable:					
DUNS:	968961354				
Proprietary Name (If Applicable) and Established Name:	Ketamine Hydrochloride Injection, USP				
Selling Unit NDC:	55150-440-10	Unit of Use NDC:	55150-440-01	UPC:	355150440108
UDI		CVX Code:		MVX Code:	
Description:	Ketamine Hydrochloride Injection, USP 1000mg/10mL (100mg/mL)				
Active Ingredient(s):	Ketamine base (as ketamine hydrochloride)				
URL for Additional Product Information:	https://eugiaus.com/products/				

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:	ANESTHETIC				

ADDITIONAL PRODUCT INFORMATION

The product is?		Is the Product…	Direct-Ship Only
a legend device?	No	Is the Product…	Unit Dose
if yes, enter class #		Orphan Drug Status	
a product kit?	No		
if yes, list NDCs of component parts		FDA Approval Status	
reverse numbered?	No		
co-licensed?	No	Allergens Present	
latex-free?	Yes		
preservative-free?	No		
correctional institution block?	No		
opioid?	No		
Cannabinoid?	No	Country of Origin	India
If Unit Dose, is item bar coded to unit dose for hospital scanning?	No	Is this product covered under the Trade Agreements Act (TAA)?	
If Unit Dose, indicate NDC here:			

PRODUCT DESCRIPTION INFORMATION

Size:	10 x 10mL Vial
Strength:	1,000 mg/10 mL
Dosage Form:	Injection
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?:	KETALAR (ketamine hydrochloride) injection

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?	Yes	GLN:	
Is product exempt from DSCSA?	No		
If yes, select exemption:		GCP:	
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?		Provide source manufacturer for repackaged product	
If yes, attach documentation from FDA.			

GTIN AND HIBCC PRODUCT INFORMATION

	Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
X	Item/Each		10		00355150440108	
	Box/Carton/Bundle/Inner Pack					
X	Case		240		50355150440103	
	Pallet				70355150440107	

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°C to 25°C (77°F)
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?	No	
Special returns requirements for this product?	No	
d. Store product (unit of sale) upright?	Yes	
Protect product (unit of sale) from light?	Yes	
e. Shelf life:	36	Months
Initial shelf life at launch (if different):		Months

ORDER INFORMATION

Unit of Sale		What is the NDC selling unit?	
	Bottle	55150-440-10	
x	Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)	
	Ampule		
	Glass	Minimum order quantity?	Yes
	Tube		
	Vial Liquid Sgl		
	Vial Liquid Multi	If Yes, how many of which package type?	
	Vial Powder Sql		Each
	Vial Power Multi		Inner/Carton/Pack
	Other: Write In	1	Case

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?		Rx billing unit to pharmacy:	
10 x 10mL Vial		X	Each
(Write-in, e.g. 1 Vial)			Gram
HCPCS J-Code:			Milliliter

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Width	Height	Volume (Cube)	Saleable # Pieces
Item/Each:	1.11525	5.31	2.16	2.55	29.247	10
Box/Carton/Bundle/ Inner Pack:						
Case:	20.83	14.56	12	6.88	1202.074	240
Pallet:	1169.35	48	40	46.34	88972.80	12960

COST INFORMATION

Regular Cost	
Invoice Cost (WAC) ($)	$133.38
As of date:	6/30/2026

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: Ariffraaje sheik

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?	No
d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)	Yes
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?	
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?	
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#

SDS Hazard Classification

x	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?	
Website URL:	
Med Guide Required	No
Limited Distribution Requirement	
Comments / Details: (For example, iPledge program?)	
REMS:	No
REMS Program Manager Name:	Phone:
Supplier Manages REMS registry exclusively:	
Wholesale distributor support:	
Provider Name:	DEA #:
Site Enrollment Number assigned by Supplier:	NCPDP#:
	NPI #:
Comments	
Registry:	No
Registry Program Contact Name:	Phone:
Comments	

ADD'L STORAGE INFORMATION

Is the Product…

Controlled Substance?	Yes	Controlled Substance Code	7285
Controlled by State(s)?	No	Listed Chemical (List I or II)	No
ARCOS Reportable?	No	If yes, indicate which:	
Schedule No.	3N	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:	

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

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:

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:

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:

Miscellaneous Notes:

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:

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:

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?

ADDITIONAL INFORMATION

Is product order for scheduled patient procedure?
Is product order for restocking purposes?