



# Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: ☐ New Item☐ Final VersionDate: 

PRODUCT INFORMATION	
Company Name:	AuroMedics Pharma LLC
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	206126
DUNS:	
Proprietary Name (If Applicable) and Established Name:	Etomidate Injection USP 20mg/10mL(2mg/mL) [10 mL SDV]
Selling Unit NDC:	55150-221-10
Individual Unit NDC:	
UDI	
CVX Code:	
UPC:	"355150221103"
MVX Code:	
Description:	Etomidate Injection USP 20mg/10mL(2mg/mL) [10 mL SDV]
Active Ingredient(s):	
URL for Additional Product Information:	www.auromedics.com
Address:	279 Princeton-Hightstown Road
City:	East Windsor
Key Contact:	
Phone Number:	888-238-7880
Product Therapeutic Classification:	

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:	
Strength:	
Dosage Form:	
Product Shape:	
Product Color:	
Product Imprint:	

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AP
II. Generic Equivalent to What Brand?:	Amidate
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

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
GLN:	035515000005
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

GTIN PRODUCT INFORMATION	
Serialized?	<input checked="" type="checkbox"/>
If not, when?	
Items aggregated?	<input checked="" type="checkbox"/>
Level	Saleable Unit
Item	2D
Box/Case/Bundle/Inner Pack	2D
Case	2D
Pallet	2D
Quantity	2D
GTIN-14	00355150221103
	10355150221100
	50355150221108
	70355150221102

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)	
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:	732-823-4122
Group E-mail:	
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):	

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

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

ITEM AND PACKING INFORMATION	
Item:	Weight Lbs. Dimensions (US msmts.) Volume (# Pieces):
	Depth Height Width (Cube)
Box/Case/Bundle/Inner Pack:	0.04284 (Carton contains 10 Vials) 5.31 2.36 2.17 #VALUE! 10
Case:	18.391 14.764 7.126 12.205 1284.06686 10 Vials = 240 Vials
Pallet:	For Sea 860.651 For Air 1191.695 For Sea 48 For Air 48 For Sea 41.02 For Air 40 For Sea 40 For Air 40 #VALUE! 10800 Vials For Sea For Air
UPC:	Case: 355150221103
Carton:	

COST INFORMATION	
Regular Cost	Vendor #:
Invoice Cost (WAC) (\$)	Whsl. Code #:
Federal Excise Tax Per Unit of Sale	Fineline Code:
As of date:	4/21/2017

\*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:

## MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Release DATE



## Standard Pharmaceutical Product Information (Page 3)

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 Information (Rx Product Only)

Introduction Type: ☐ New Item☐ Final VersionDate: 

PRODUCT INFORMATION	
Company Name:	AuroMedics Pharma LLC
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	206126
DUNS:	
Proprietary Name (If Applicable) and Established Name:	Etomidate Injection USP 40mg/20mL(2mg/mL) [20 mL SDV]
Selling Unit NDC:	55150-222-20
UDI	
Individual Unit NDC:	
CVX Code:	
UPC:	"355150222209"
MVX Code:	
Description:	Etomidate Injection USP 40mg/20mL(2mg/mL) [20 mL SDV]
Active Ingredient(s):	
URL for Additional Product Information:	www.auromedics.com
Address:	279 Princeton-Hightstown Road
City:	East Windsor
Key Contact:	
Phone Number:	888-238-7880
Product Therapeutic Classification:	

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:	
Strength:	
Dosage Form:	
Product Shape:	
Product Color:	
Product Imprint:	

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AP
II. Generic Equivalent to What Brand?:	Amidate
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

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
GLN:	035515000005
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

GTIN PRODUCT INFORMATION	
Serialized?	<input checked="" type="checkbox"/>
If not, when?	
Items aggregated?	<input checked="" type="checkbox"/>
Level	Saleable Unit
Item	2D
Box/Case/Bottle/Inner Pack	2D
Case	2D
Pallet	2D
Quantity	2D
GTIN-14	2D
00355150222209	2D
10355150222206	2D
50355150222204	2D
70355150222208	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)	
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:	732-823-4122
Group E-mail:	
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):	

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

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

ITEM AND PACKING INFORMATION			
Weight Lbs.	Dimensions (US msmts.)	Volume (Cube)	# Pieces:
Depth	Height	Width	
Item:			0
Box/Case/Bottle/Inner Pack:	10355150222209	10355150222206	10355150222204
Case:	13.724	15.157	15.157
Pallet:	For Sea 691.801	For Sea 48	For Sea 40
UPC:	Case:	Carton:	"355150222209"

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$63.50	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:	4/21/2017		

\*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:

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? ☐ No

- c. Contact Hazard? ☐ No
- 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 or 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#

## 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

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
- ☐ 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?

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

## RETURN INSTRUCTIONS

Contact tel. # if product 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 and/or Image of Product Barcode:

Release DATE



## Standard Pharmaceutical Product Information (Page 3)

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>