



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: New Item Final VersionDate:

PRODUCT INFORMATION	
Company Name:	AuroMedics Pharma LLC
Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	209144
DUNS:	968961354
Proprietary Name (If Applicable) and Established Name:	CISATRACURIUM BESYLATE INJECTION 20 mg/10 mL(2 mg/mL) Multiple Dose Vial (10's)
Selling Unit NDC:	55150-286-10
Individual Unit NDC:	55150-286-01
UPC:	355150286102
UDI	
CVX Code:	
MVX Code:	
Description:	CISATRACURIUM BESYLATE INJECTION 20 mg/10 mL(2 mg/mL) Multiple Dose Vial (10's)
Active Ingredient(s):	CISATRACURIUM BESYLATE
URL for Additional Product Information:	
Address:	279 Princeton-Hightstown Road
City:	East Windsor
Key Contact:	
Phone Number:	888-238-7880
Product Therapeutic Classification:	
State:	NJ
Address 2:	
Email:	
Zip:	08520
Fax:	732-355-9449

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
Temperature Range	Cold – between 2 and 8 C (36° – 46° F)
Other Temperature Range Requirement (write in)	Store at 2° - 8° C (36° - 46° F) in the
Is this product to be shipped to customers on ice?	Yes
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:	slucas@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?	No
Protect product (unit of sale) from light?	No
e. Shelf life:	
Initial shelf life at launch (if different):	18 Months

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... Neither	
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input checked="" type="checkbox"/>
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 Multi Dose Vials
Strength:	20 mg/10 mL(2 mg/mL)
Dosage Form:	LIQUID
Product Shape:	Vial Pack
Product Color:	
Product Imprint:	

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input type="checkbox"/> Bottle	1 box of 10 vials
<input checked="" type="checkbox"/> Box/Carton	(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?
	<input type="checkbox"/> Each
	<input type="checkbox"/> Inner/ Carton/Pack
	<input checked="" type="checkbox"/> Case

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

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="text" value="10 vials"/>	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
	<input type="checkbox"/> Milliliter

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:	
If Yes, was original product purchased direct from mfr?	<input checked="" type="checkbox"/>
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.) Depth Height Width	Volume (Cube)	# Pieces:		
Item:	0.044	5.31 2.36 2.17	27.193572	10 vials		
Box/Carton/Bundle/Inner Pack:	3.0643	13.82 2.99 5.75	237.60035	60 vials		
Case:	13.812	14.763 7.323 12.205	1319.47583	240 vials		
Pallet:	Sea: 654.587 Air: 903.211	48	Sea: 41.85 Air: 56.50	40	#VALUE!	10800 vials
UPC:	Case:	50355150286107				
	Carton:	00355150286102				

GTIN PRODUCT INFORMATION						
Serialized?	Level	Saleable Unit	Quantity	GTIN-14		
Yes	<input checked="" type="checkbox"/> Item		10	00355150286102	<input checked="" type="checkbox"/> 2D	Linear
If not, when?	<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	<input checked="" type="checkbox"/>	60	30355150286103	<input checked="" type="checkbox"/> 2D	Linear
Items aggregated?	<input checked="" type="checkbox"/> Case		240	50355150286107	<input checked="" type="checkbox"/> 2D	Linear
	<input checked="" type="checkbox"/> Pallet		10800	70355150286101	<input checked="" type="checkbox"/> 2D	Linear
					<input type="checkbox"/> 2D	Linear
					<input type="checkbox"/> 2D	Linear
					<input type="checkbox"/> 2D	Linear

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$230.00	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:			

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? 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 No

Restricted to retail pharmacy only: No

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

Restricted from US territories? (explain in comments)

Comments:

SDS Hazard Classification

<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard

Aerosol Class; Identify NFPA Storage Level:

Is the product a NIOSH hazardous drug? No

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: No

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: Yes

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:

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> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%;">a. EDI</td> <td style="width: 25%;"><input type="text"/></td> <td style="width: 25%;"></td> <td style="width: 25%;"></td> </tr> <tr> <td>b. Autofax</td> <td><input type="text"/></td> <td>Fax Number:</td> <td><input type="text"/></td> </tr> <tr> <td>c. Fax</td> <td><input type="text"/></td> <td>Fax Number:</td> <td><input type="text"/></td> </tr> <tr> <td>d. Phone only</td> <td><input type="text"/></td> <td>Phone No.:</td> <td><input type="text"/></td> </tr> <tr> <td>e. Supplier Web Site only</td> <td><input type="text"/></td> <td>Site Address:</td> <td><input type="text"/></td> </tr> </table> <p>Minimum Order Quantity: <input style="width: 80%;" type="text"/></p> <p>Supplier's Customer Service Number: <input style="width: 95%;" type="text"/></p> <p>Contracted 3PL company / contact #:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Name:</td> <td><input style="width: 80%;" type="text"/></td> </tr> <tr> <td>Phone:</td> <td><input style="width: 80%;" type="text"/></td> </tr> </table>	a. EDI	<input type="text"/>			b. Autofax	<input type="text"/>	Fax Number:	<input type="text"/>	c. Fax	<input type="text"/>	Fax Number:	<input type="text"/>	d. Phone only	<input type="text"/>	Phone No.:	<input type="text"/>	e. Supplier Web Site only	<input type="text"/>	Site Address:	<input type="text"/>	Name:	<input style="width: 80%;" type="text"/>	Phone:	<input style="width: 80%;" type="text"/>	<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input style="width: 60%;" type="text"/></p> <p>Shipping lead time of PO: <input style="width: 30%;" type="text"/> Hours <input style="width: 30%;" type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>
a. EDI	<input type="text"/>																								
b. Autofax	<input type="text"/>	Fax Number:	<input type="text"/>																						
c. Fax	<input type="text"/>	Fax Number:	<input type="text"/>																						
d. Phone only	<input type="text"/>	Phone No.:	<input type="text"/>																						
e. Supplier Web Site only	<input type="text"/>	Site Address:	<input type="text"/>																						
Name:	<input style="width: 80%;" type="text"/>																								
Phone:	<input style="width: 80%;" type="text"/>																								
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing																								
<p>Expedited freight fees billed with each order: <input style="width: 60%;" type="text"/></p> <p>Drop Ship service fee billed with each order: <input style="width: 60%;" type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input style="width: 60%;" type="text"/></p> <p>Comments: <input style="width: 95%; height: 40px;" type="text"/></p>	<p>Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt cut off time: <input style="width: 60%;" type="text"/></p> <p>Days of week overnight is available:</p> <table style="width: 100%; border-collapse: collapse;"> <tr><td><input type="checkbox"/> Monday</td></tr> <tr><td><input type="checkbox"/> Tuesday</td></tr> <tr><td><input type="checkbox"/> Wednesday</td></tr> <tr><td><input type="checkbox"/> Thursday</td></tr> <tr><td><input type="checkbox"/> Friday</td></tr> </table> <p>Priority Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input style="width: 60%;" type="text"/></p> <p>Saturday Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input style="width: 60%;" type="text"/></p> <p>Order receipt method:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Phone:</td> <td style="width: 40%;"><input style="width: 95%;" type="text"/></td> <td style="width: 20%;">Phone #:</td> <td style="width: 20%;"><input style="width: 95%;" type="text"/></td> </tr> <tr> <td>Fax:</td> <td><input style="width: 95%;" type="text"/></td> <td>Fax #:</td> <td><input style="width: 95%;" type="text"/></td> </tr> <tr> <td>EDI:</td> <td><input style="width: 95%;" type="text"/></td> <td></td> <td></td> </tr> </table> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>	<input type="checkbox"/> Monday	<input type="checkbox"/> Tuesday	<input type="checkbox"/> Wednesday	<input type="checkbox"/> Thursday	<input type="checkbox"/> Friday	Phone:	<input style="width: 95%;" type="text"/>	Phone #:	<input style="width: 95%;" type="text"/>	Fax:	<input style="width: 95%;" type="text"/>	Fax #:	<input style="width: 95%;" type="text"/>	EDI:	<input style="width: 95%;" type="text"/>									
<input type="checkbox"/> Monday																									
<input type="checkbox"/> Tuesday																									
<input type="checkbox"/> Wednesday																									
<input type="checkbox"/> Thursday																									
<input type="checkbox"/> Friday																									
Phone:	<input style="width: 95%;" type="text"/>	Phone #:	<input style="width: 95%;" type="text"/>																						
Fax:	<input style="width: 95%;" type="text"/>	Fax #:	<input style="width: 95%;" type="text"/>																						
EDI:	<input style="width: 95%;" type="text"/>																								
Class of Trade Restriction:																									
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input style="width: 95%; height: 40px;" type="text"/></p>																									
Other Data Information Required to Process PO:	Return Instructions																								
<p>Patient Procedure Date: <input style="width: 60%;" type="text"/></p> <p>Physician Name: <input style="width: 95%;" type="text"/></p> <p>Physician/Clinic Phone #: <input style="width: 95%;" type="text"/></p> <p>Physician State License #: <input style="width: 95%;" type="text"/></p> <p>Physician/Clinic DEA #: <input style="width: 95%;" type="text"/></p> <p>Physician/Clinic Specialty: <input style="width: 95%;" type="text"/></p>	<p>Contact # if product is received damaged: <input style="width: 60%;" type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input style="width: 95%;" type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input style="width: 95%; height: 40px;" type="text"/></p>																								
Miscellaneous Notes:	ADDITIONAL INFORMATION																								
<input style="width: 95%; height: 60px;" type="text"/>	<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>																								