

# **Standard Pharmaceutical Product Information (Rx Product Only)**

					Introduction	Type:	New Item		Final Version			Date:			
			PRODUCT INFORMATION						SPECIAL HANDLI	NG AND STO	DRAGE REQ	UIREMENTS	•		
Company Name: AuroMedics Pharma LLC Application: ANDA							a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 206126								Temperature Range Controlled Room – between 20 and 25 C (68° – 77° f							
DUNS:						Other Temperature Range Requirement									
Proprietary Name (If Applicable) and Established Name: Etomidate Injection USP 20mg/10mL(2mg/mL) [10 mL SDV]							(write in)								
Selling Unit NDC:	55150-221-10		Individual Unit NDC:		UPC:	"3551502211	03"								
UDI CVX Code: MVX Code:						Is this product to be shipped to customers on ice?  No									
Description: Etomidate Injection USP 20mg/10mL(2mg/mL) [10 mL SDV]								Is this product to be shipped to customers on dry ice?  No							
Active Ingredient(s):								b. Contact for tempera	tura avaluraian allac	tions:					
Active ingredient(s).								Name:	ture excursion ques	tions.	Steve Lucas	1			
URL for Additional Product In	nformation:	www.auromedics.com						Number	:		732-823-412				
Address:	279 Princeton-Hightst	own Road			Address 2:			Group E	-mail:						
City:	East Windsor			State:	NJ	Zip:	08520								
Key Contact:	888-238-7880			Email: Fax:	732-355-9449			c. Special regulations for product in any states?							
Phone Number: Product Therapeutic Classifi				rax.	732-355-9449			Special returns requirements for this product?  No							
Froduct Therapeutic Classiii	cation.							d. Store product (unit of	of sale) unright?				Yes		
ADDITIONA	L PRODUCT INFORM	ATION		F	PRODUCT DESCR	IPTION INFORM	MATION		product (unit of sale	) from light?		-	No		
Is the Product			TRODUCT DECORATION IN CRIMATION					e. Shelf life:	,	24			Months		
a legend device?		No							nelf life at launch (if	different):		•	27	Months	
reverse numbered?		No		Size:						,-		L			
co-licensed?		No		Strength:					0	RDER INFOR	RMATION				
Is the Product		Direct-Ship Only		Ou chigan.											
Is the Product				Dosage Form	:			Unit of S			10 vials in o	NDC selling	unit?		
								x	Bottle Box/Carton			g. 1 Box of 10	) \/iale\		
If Unit Dose, is item bar code	d to unit dose for hospi	tal scanning?						<u> </u>	Ampule		(write-iii, e	g. I box of it	, viais)		
If Unit Dose NDC, indicate NI	DC here:			Product Shap	e:			Glass Minimum order quantity? Yes							
Product Color:									Tube				•		
Country of Origin		India						Vial Liquid Sgl Vial Liquid Multi If Yes, how many of which package type?							
Is this product covered under	the Trade Agreements	Act (TAA)?		Product Impri	int:			Vial Powder Sql Each							
<u> </u>								Vial Power Multi		24	Inner/Carton	Pack Pack			
								Other: Write In	-		Case				
			FOR GENERIC DRUG PRODUCTS	5						1					
				Auth	orized Generic	*If Authorized	I Generic, other section		PHAR	MACY ORDE	R / BILL UN	Т			
I. Orange Book Rating:	AP			7100.1	0.1.204 00110110	fields are not		Rec. sell unit to custor				nit to pharma	ocv.		
I. Generic Equivalent to What Brand?: Amidate						Each									
<u></u>										_		Gram			
		DRUG SUPPLY	CHAIN SECURITY ACT (DSCSA)	INFORMATION								Milliliter			
Does supplier meet DSCSA of	definition of manufact	uror?	Yes	GLN:	0355150000005				ITEM AN	ID PACKING	INFORMAT	ON			
Is product exempt from DSC			lo	OLN.	000010000000										
If yes, select exemption:									Weight Lbs.		nsions (US n	-	Volume	# Pieces:	
Other exemption - Write in:								-	g.n. 220.	Depth	Height	Width	(Cube)		
Is product repackaged? Is product sold by manufactu	urar'e avalueiva dietrik		No No	If Yes, was origin from mfr?	al product purcha	sed direct		Item:					0		
Has FDA granted waiver/exc			No	If yes, attach doc	umentation from F	DA.		Box/Carton/Bundle/	0.04204 (Carton	TOS CARTON	TUS CARTON	TO S CARTON			
								Inner Pack:	contains 10 Vials)	5.31 F-Flute Box	2.36 E-Flute Box	2.17 F-Flute Box	#VALUE!	10	
			GTIN PRODUCT INFORMATION					Case:	18.391	14.764	7.126	12.205	1284.06686	10 Vials =	
			Saleable Level Unit	•		Quantity	GTIN-14	Pallet:	For Sea 860.651	For Sea 48	FUI Sea	For Sea 40		240 Vials	
Serialized?		х	Item	2D	Linear		00355150221103	rallet.	For Air 1191.695	For Air 48	41.02	For Air 40	#VALUE!	10800 Vials	
If not, when?			Box/Carton/Bundle/Inner Pack 10s	2D	Linear		10355150221100	UPC:	Case:		FOR AIR			FOR AIR	
Items aggregated?		х	Case	2D	Linear		50355150221108		Carton:	3551502211	103				
		х	Pallet	2D	Linear		70355150221102								
		<u> </u>		2D	Linear			COST	INFORMATION			WHOLESAL	ER USE ONL	Υ:	
				2D 2D	Linear			Regular Cost			Vendor #:	Г			
				2D Linear						) Whsl. Code #:					
						L L		Federal Excise Tax Pe		ψ55.00	Fineline Co				
								As of date:	4/21/2017	•	]	,			
			tach copy of SAFETY DATA SHEE	T (SDS) or non haz											
*Please provide any addition	al information on pag	e 2.			See new p. 3 for	r Designated Dr	op Ship Only.	Signatu	re:						



### **Standard Pharmaceutical Product Information (Page 2)**

For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): SDS Hazard Classification a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? No Inorganic Oxidizer Does the product label bear a CA Prop 65 warning? No Steroid/Androgen Contact Hazard c. Contact Hazard? No Aerosol Class; Identify NFPA Storage Level: d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) Is the product a NIOSH hazardous drug? e. Does the product contain DEHP? No If yes, indicate which: Is this product regulated for shipment by DOT or IATA? No (if yes, answer a-e below and provide SDS) a. UN/Identification Number Hazardous Waste Identification b. Proper Shipping Name c. DOT Hazard Class EPA Hazardous Waste Code: d. Packing Group e. Inhalation Hazard? REMS or REGISTRY RESTRICTIONS Is the product restricted for air shipment? If so, indicate restriction: Passenger Is there a REMS on this product? Cargo If Yes, is it managed with a pharmacy registry? Passenger & Cargo Website URL: Is this a reportable quantity? RQ Threshold: Comments / Details: (For example, iPledge program?) Is this a marine pollutant? Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below) REMS: REMS Program Manager Name: Limited Quantity Phone: Consumer Commodity, ORM-D Supplier Manages REMS registry exclusively: Small Quantity (49 CFR 173.4) Wholesale distributor support: Special Permit: DOT-SP Provider Name: Site Enrollment Number assigned Special Provision (listed in Column 7 of 49 CFR 172.101); DEA #: by Supplier: SP# PCPDP #: NPI#: ADD'L STORAGE INFORMATION Is the Product... Comments Controlled Substance? No Controlled by State(s)? No Registry: ARCOS Reportable? No Registry Program Contact Name: Schedule No. (inc. N for non-narcotic) Comments Controlled Substance Code Listed Chemical (List I or II) No RETURN INSTRUCTIONS If yes, indicate which: Is it a scheduled listed chemical product?: No Contact tel. # if product received damaged: CLASS OF TRADE RESTRICTION: Is product returnable for credit: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices URL/Link to returns policy: Restricted to retail pharmacy only: Special regulations or returns requirements for this product in certain states? Restricted to hospital, clinics, and physician offices only: If so, which states? Other requirements? Comments? Restricted from US territories? (explain in comments) Comments: MISCELLANEOUS NOTES and/or Image of Product Barcode:



## **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						
Purchase orders may be accepted by:  a. EDI	Purchase order daily receipt cut off time by supplier Cut off time:						
b. Autofax Fax Number: c. Fax d. Phone only e. Supplier Web Site only  Fax Number: Phone No.: Site Address:	Shipping lead time of PO: Hours Days  Ships same day for next day receipt:						
Minimum Order Quantity:  Supplier's Customer Service Number:  Contracted 3PL company / contact #:  Phone:	Ships for second day receipt: Ships regular ground for 3-10 days receipt:						
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing						
Expedited freight fees billed with each order:	Overnight receipt available:						
Drop Ship service fee billed with each order:	PO Receipt cut off time:						
Drop Ship miscellaneous fees billed:  Comments:	Days of week overnight is available:  Monday Tuesday Wednesday Thursday Friday						
	Priority Overnight receipt available:						
Class of Trade Restriction:	PO Receipt Cut off time:						
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:	Saturday Overnight receipt available:  PO Receipt Cut off time: Phone: Fax: EDI:  Overnight Fees apply: Other fees apply:						
Other Data Information Required to Process PO:	Return Instructions						
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:	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?						
Miscellaneous Notes:							
	ADDITIONAL INFORMATION						
	Is product order for scheduled patient procedure? Is product order for restocking purposes?						



# **Standard Pharmaceutical Product Information (Rx Product Only)**

Product   Prod						Introduction	Туре:	New Item		Final Version			Date:			
### Application Number for Post/ASSPECAN   Progress   P				PRODUCT INFORMATION						SPECIAL HANDLI	ING AND ST	ORAGE REQ	UIREMENTS	*		
DBMS:   State   Control																
Marchest plant Relation   Marchest plant R		A/ANDA/BLA (drug); F	PMA/510(k)(med device):		206126				•	=		Controlled F	oom – betwe	en 20 and 25	C (68° – 77° I	
Selection   Sele																
Active ingression(s)								(with in)								
Contact in regulation accordance to the residence of the product							Is this product to be shipped to customers on ice?									
Manage   M	Description:	Etomidate Injection US	SP 40mg/20mL(2mg/mL) [	20 mL SDV]					Is this product to be shipped to customers on dry ice? No							
State   Contract   C	Active Ingredient(s):								1	•	stions:	Steve Lucas	5			
Source   S	URL for Additional Product I	nformation:	www.auromedics.com													
Enterly   Ente			own Road		01-1-		7	=00	Group	o E-mail:						
Special review (page 1   1		East Windsor				NJ	Zip:   U8:	520	c. Special regulations for product in any states?							
AGOITO/ALL PRODUCT BROWNTON   Size:		888-238-7880				732-355-9449						ict?	-			
Product product and of sell from glight   To   No mins   To   No m	Product Therapeutic Classif	ication:							1							
Seption devices   Seption de	ADDITIONA	AL PRODUCT INFORM	ATION		F	PRODUCT DESCRI	PTION INFORMAT	ΓΙΟΝ			) from light?	>	-			
a larged device? No reviewer number of 1 10-10-10-10-10-10-10-10-10-10-10-10-10-1										or product (arm or oalo	,		ī		Months	
Strength:    Design Step Orly					Sizo:					shelf life at launch (if	different):		İ		Months	
Seriolate  In the Product  Is the Product  Is the Product  Is the Product Shape:    Froduct Shape:   Product Shap					Oize.						DDED INCO	DMATION				
If Usin Does, is term bar cooled to unit dose for hospital scanning?  If Usin Does, is term bar cooled to unit dose for hospital scanning?  Froduct Shape:    Product Shape:					Strength:					U	KDEK INFO	RWATION				
If Unit Doos, is tem bar coded to unit does for hospital scanning?  If Unit Doos, is tem bar coded to unit does for hospital scanning?  If Unit Doos, is tem bar coded to unit does for hospital scanning?  If Unit Doos, is tem bar coded to unit does for hospital scanning?  If Unit Doos, is tem bar coded to unit does for hospital scanning?  If Unit Doos, is tem bar coded to unit does for hospital scanning?  If Unit Doos, is tem bar coded to unit does for hospital scanning?  If Unit Doos, is tem bar coded to unit does for hospital scanning.  If Unit Doos, is tem bar coded to unit does for hospital scanning.  If Unit Doos, is tem bar coded to unit does for hospital scanning.  If Unit Doos, is tem bar coded to unit does for hospital scanning.  If Unit Doos, is tem bar coded to unit does for hospital scanning.  If Unit Doos NDC, indicate NDC here:  If Unit Doos N	Is the Product				Dosage Form				Unit o					unit?		
Tributh Does NDC, decided NDC here:									<u> </u>					O Viole)		
## Country of Origin   In the Dec NDC, indicate NDC here:	If Unit Dose, is item bar code	ed to unit dose for hospi	ital scanning?		Braduat Shan				<del>  ^</del>			(vviite-iii, e	g. I box of it	) viais)		
L Crange Book Rating II. Generic Equivalent to What Brand?    Authorized Generic   The Authorize	If Unit Dose NDC, indicate N	DC here:			Froduct Snap	Je.										
Serial product covered under the Trade Agreements Act (TAA)? No   Product Imprint:	Country of Origin		India		Product Colo	r:			-							
Visit   Provider Sign   Case			2 Δct (ΤΔΔ)2		Product Impri	int·			Vial Liquid Multi If Yes, how many of which package type?							
FOR GENERIC DRUG PRODUCTS    Authorized Generic   Authorized Generic   Til Authorized Generic	No N									10		/Deels				
L. Orange Book Rating: Amidate    Comparison   Amidate									10		Pack					
1. Generic Equivalent to What Brand?:   Amidate   Supply CHAIN SECURITY ACT (DSCSA) INFORMATION				FOR GENERIC DRUG PRODUCT	TS						1		'			
1. Generic Equivalent to What Brand?:   Amidate   Supply CHAIN SECURITY ACT (DSCSA) INFORMATION					Auth	orized Generic	*If Authorized Ge	eneric, other section		PHAR	MACY ORDE	ER / BILL UN	T			
Serialized?   For Air April   For See Set Set Serialized?   For Air April	I. Orange Book Rating:	AP							Rec. sell unit to cus							
Does supplier meet DSCSA definition of manufacturer?   Yes											Each	•				
Does supplier meet DSCSA definition of manufacturer?   Yes	DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION								(Write-in, e.g. 1 Vial)			-				
Seption   Sept			51100 001 1 21	0.0000	<u> </u>											
Tyes, select exemption:					GLN:	0355150000005				ITEM A	ND PACKING	SINFORMAT	ION			
Serialized?   No		JA!		10						Mainhe I ha	Dime	nsions (US n	ısmts.)	Volume	# Diagon.	
Sproduct sold by manufacturer's exclusive distributor?   No   from mfr?										weight Lbs.	Depth	Height	Width	(Cube)	# Pieces:	
Ras FDA granted waiver/exception/exemption for product?   No   If yes, attach documentation from FDA.		urer's exclusive distrib				al product purchas	sed direct		Item:					0		
Case					If yes, attach doc	umentation from Fl	DA.			contains 10 Vials)	6 50	2 76	10 S Carton 2 68	#\/ALLIE!	10	
Saleable   Cevel   Unit   CTIN-14   Serialized?   If not, when?   Items aggregated?				GTIN PRODUCT INFORMATIO	N				.	5 948 (3 Ply Box	E-Flute Box	F-Flute Box	E-Flute Box			
Serialized?									Case.	13.724	15.157	5.118	15.157	1175.78193		
If not, when?	Carializado								Pallet:			46.34		#VALUE!	4800 Vials	
Items aggregated?									UPC:		FUI All 46	For Air	FOI All 40		For Air 6000	
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.  COST INFORMATION  WHOLESALER USE ONLY:  Vendor #:  Invoice Cost (WAC) (\$)  \$63.50  Whsl. Code #:  Federal Excise Tax Per Unit of Sale  As of date:  Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.	Items aggregated?								"355150222	2209"						
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.  Regular Cost   Vendor #:   Vendor #:     Vendor #:     Vendor #:     Vendor #:     Vendor #:     Vendor #:     Vendor #:   Vendor								COS	ST INFORMATION			WHOLESAL	FR USE ONL	γ		
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.    Invoice Cost (WAC) (\$)			<del></del>						- 000	THE ORINATION			MOLLOAL	EN-OOL ONE		
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.																
As of date: 4/21/2017  Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.		L J2D Linear L Linear														
												1	[			
									1							
	*Please provide any addition	nal information on page		tach copy of SAFETY DATA SHE	ET (SDS) or non haz											



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Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing						
Purchase orders may be accepted by:  a. EDI	Purchase order daily receipt cut off time by supplier Cut off time:						
b. Autofax Fax Number: c. Fax d. Phone only e. Supplier Web Site only  Fax Number: Phone No.: Site Address:	Shipping lead time of PO: Hours Days  Ships same day for next day receipt:						
Minimum Order Quantity:  Supplier's Customer Service Number:  Contracted 3PL company / contact #:  Phone:	Ships for second day receipt: Ships regular ground for 3-10 days receipt:						
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing						
Expedited freight fees billed with each order:	Overnight receipt available:						
Drop Ship service fee billed with each order:	PO Receipt cut off time:						
Drop Ship miscellaneous fees billed:  Comments:	Days of week overnight is available:  Monday Tuesday Wednesday Thursday Friday						
	Priority Overnight receipt available:						
Class of Trade Restriction:	PO Receipt Cut off time:						
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:	Saturday Overnight receipt available:  PO Receipt Cut off time: Phone: Fax: EDI:  Overnight Fees apply: Other fees apply:						
Other Data Information Required to Process PO:	Return Instructions						
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:	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?						
Miscellaneous Notes:							
	ADDITIONAL INFORMATION						
	Is product order for scheduled patient procedure? Is product order for restocking purposes?						