

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

					Introduction	Type:	New Item		Final Version			Date:	20.01	.2018	
			PRODUCT INFORMATION						SPECIAL HANDL	ING AND STO	DRAGE REQU	JIREMENTS	*		
Company Name: AuroMedics Pharma LLC Application: ANDA							a. Temperature – Indicate the USP temperature range for this product.								
Application Number for ND	umber for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 205331							Temperature Range Controlled Room – between 20 and 25 C (68° – 77° I							
DUNS:	968961354						Other Temperature Range Requirement								
Proprietary Name (If Applical	etary Name (If Applicable) and Established Name: Adenosine Injection, USP 60 mg per 20 mL (3 mg/mL) [20 mL Single Dose Vial]							(write in) Store at 20° to 25°C (68° to 77°F).							
Selling Unit NDC: 55150-192-20 Individual Unit NDC: 55150-192-20 UPC: '355150192205							05	le this product to be chipped to quetomers as issa							
UDI CVX Code: MVX Code:						Is this product to be shipped to customers on ice?									
Description: Adenosine Injection, USP 60 mg per 20 mL (3 mg/mL) [20 mL Single Dose Vial]								Is this product to be shipped to customers on dry ice?							
Active Ingradients)							b. Contact for temperature excursion questions:								
Active Ingredient(s):								Name:	iture excursion ques	itions.					
URL for Additional Product Information: www.auromedics.com								Number	:						
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				732-330-9449				Special returns requirements for this product?  No							
Froduct Therapeutic Classiii	cation.							d Store product (unit	of sale) unright?				Yes		
ADDITIONA	L PRODUCT INFORM	ATION	1	Р	RODUCT DESCRI	PTION INFORM	MATION	d. Store product (unit of sale) upright?  Protect product (unit of sale) from light?  No							
Is the Product			THE STATE OF THE CHARLES OF THE CHAR					e. Shelf life:					24 Months		
a legend device?		No					10.1							Months	
reverse numbered?		No	Size:		10 x 20 r	10 x 20 mL Single Dose Vials		I amorony.							
co-licensed?		No	Strength: 60 mg per 20 mL (3 mg/mL)					ORDER INFORMATION							
Is the Product		Direct-Ship Only		<b>-</b>							140	NDO III			
Is the Product				Dosage Form:	: LIQUID			Unit of S	Bottle		What is the 55150-192-2		unit?		
								x	Box/Carton		(Write-in, e.g		0 Vials)		
If Unit Dose, is item bar code	d to unit dose for hospi	tal scanning?		Product Shape	e: Vial Pac	<b>V</b>		Ampule							
If Unit Dose NDC, indicate NI	DC here:			r roudet onap	viai i ac			Glass Minimum order quantity?							
Country of Origin		India		Product Color	r:				Tube Vial Liquid Sgl						
								Vial Liquid Ggi  Vial Liquid Multi If Yes, how many of which package type?							
Is this product covered under the Trade Agreements Act (TAA)? No Product Imprint:							Vial Powder Sql		1	Each		,,			
								Vial Power Multi			Inner/Carton	/Pack			
FOR GENERIC DRUG PRODUCTS								Other: Write In	1	100	Case				
				Autho	orized Generic		d Generic, other section								
I. Orange Book Rating: AP			fields are not applicable				Rec. sell unit to customer?			Rx billing unit to pharmacy:					
II. Generic Equivalent to What Brand?:  Adenoscan								(Misteria e a 4 Miel)				Each Gram			
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION								(Write-in, e.g. 1 Vial)				Milliliter			
Does supplier meet DSCSA definition of manufacturer?  Is product exempt from DSCSA?  No  O355150000005  O355150000005									ITEM AI	ND PACKING	INFORMATI	ON			
Is product exempt from DSC If yes, select exemption:	SA?		10					Dime			ensions (US msmts.) Volume				
Other exemption - Write in:									Weight Lbs.	Depth	Height	Width	(Cube)	# Pieces:	
Is product repackaged?		N			al product purcha	sed direct		Item:					0		
Is product sold by manufactu				from mfr?				- 10							
Has FDA granted waiver/exc	eption/exemption for p	product?	No	If yes, attach docu	umentation from F	DA.		Box/Carton/Bundle/ Inner Pack:	5.82	14.02	3.94	7.13	393.852644	one E-Flute b	
			GTIN PRODUCT INFORMATION					Case:							
			Saleable						13.114	15.157	5.118	15.157	1175.78193	x, 2 E-Flute b	
			Level Unit				GTIN-14	Pallet:	Sea: 583.836	48	Sea: 40.83	40	#VALUE!	10 Vials in	
Serialized? If not, when?			Item X  Box/Carton/Bundle/Inner Pack	2D 2D	Linear 10		10355150192202 30355150192206	UPC:	Air: 741.206 Case:	5035515019	Air: 51.06			Carton 5	
Items aggregated?			Case	2D	Linear			ll orc.	Carton:	1035515019					
items aggregated:			Pallet	2D	Linear	4200	70355150192204								
2D Unear						COST INFORMATION WHOLESALER USE ONLY:									
	2D Linear								ļ						
	2D Linear 2D Linear						Regular Cost								
			2D Linear				Invoice Cost (WAC) (\$) \$960.00 Federal Excise Tax Per Unit of Sale			Fineline Code:					
								As of date:	2/9/2018	-	emie COC				
			ttach copy of SAFETY DATA SHEET	(SDS) or non haza											
*Please provide any addition	al information on pag	e 2.			See new p. 3 for	Designated Dr	rop 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 888-238-7880 Contact tel. # if product received damaged: CLASS OF TRADE RESTRICTION: Is product returnable for credit: Yes http://auromedics.com/policies/return-policy/ 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)**

					Introduction	Type:	New Item		Final Version			Date:	20.01	.2018		
			PRODUCT INFORMATION						SPECIAL HANDLI	NG AND STO	DRAGE REQU	JIREMENTS	;*			
Company Name: AuroMedics Pharma LLC Application: ANDA							a. Temperature – Indicate the USP temperature range for this product.									
Application Number for ND	ımber for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 205331						Temperature Range Controlled Room – between 20 and 25 C (68° – 77° I									
DUNS:	968961354					Other Temperature Range Requirement										
Proprietary Name (If Applica	tary Name (If Applicable) and Established Name: Adenosine Injection, USP 90 mg per 30 mL (3 mg/mL) [30 mL Single Dose Vial]							(write in) Store at 20° to 25°C (68° to 77°F).								
Selling Unit NDC:         55150-193-30         Individual Unit NDC:         55150-193-30         UPC:         '355150193301							301									
UDI CVX Code: MVX Code:						Is this product to be shipped to customers on ice?										
Description: Adenosine Injection, USP 90 mg per 30 mL (3 mg/mL) [30 mL Single Dose Vial]								Is this product to be shipped to customers on dry ice?								
Active Ingradients)							b. Contact for tempera	tura avauraian auaa	tions							
Active Ingredient(s):								Name:	ture excursion ques	illons.						
URL for Additional Product Information: www.auromedics.com								Number								
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			1 ax. [/32-330-9449					Special returns requirements for this product?  No								
Froduct Therapeutic Classiii	cation.							d Store product (unit a	of sale) unright?				Yes			
ADDITIONA	L PRODUCT INFORM	ATION		Р	RODUCT DESCR	IPTION INFORM	MATION	d. Store product (unit of sale) upright?  Protect product (unit of sale) from light?  No								
Is the Product								e. Shelf life:	24 Months			Months				
a legend device?		No					10.1	Initial shelf life at launch (if different):					Months			
reverse numbered?		No	Size:		10 x 30 i	10 x 30 mL Single Dose Vials		I amoralisti ino at idanon (ii amoralis).								
co-licensed?		No	Strength: 90 mg per 30 mL (3 mg/mL)					ORDER INFORMATION								
Is the Product		Direct-Ship Only		<b>-</b>			,				140	NDO III				
Is the Product				Dosage Form:	LIQUID			Unit of S	Bottle		What is the 55150-193-3		unit?			
								x	Box/Carton		(Write-in, e.		0 Vials)			
If Unit Dose, is item bar code	d to unit dose for hospi	tal scanning?		Product Shape: Vial Pack				Ampule		,,	,	,				
If Unit Dose NDC, indicate N	DC here:			r roudet onap	C. Viai i ac	i.		Glass Minimum order quantity?								
Country of Origin		India		Product Color	r:				Tube Vial Liquid Sgl							
								Vial Liquid Ggi  Vial Liquid Multi If Yes, how many of which package type?								
Is this product covered under the Trade Agreements Act (TAA)? No Product Imprint:								Vial Powder Sql		1	Each		,,			
								Vial Power Multi			Inner/Carton	/Pack				
FOR GENERIC DRUG PRODUCTS								Other: Write In	1	100	Case					
										_						
				Autho	orized Generic		d Generic, other section		PHAR	MACY ORDE	R / BILL UNI	Т				
I. Orange Book Rating: AP			fields are not applicable				Rec. sell unit to customer?			Rx billing unit to pharmacy:						
II. Generic Equivalent to What Brand?:  Adenoscan								(Maite in a a 4 Viel)				Each Gram				
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							(Write-in, e.g. 1 Vial)				Milliliter					
Does supplier meet DSCSA definition of manufacturer? Yes GLN: 0355150000005								ITEM AND PACKING INFORMATION								
Is product exempt from DSC If yes, select exemption:	SA?		No .					Dim			ensions (US msmts.) Volume # 5					
Other exemption - Write in:							Ī		Weight Lbs.	Depth	Height	Width	(Cube)	# Pieces:		
Is product repackaged?		N		If Yes, was origina	al product purcha	sed direct		Item:					0			
Is product sold by manufactu				from mfr?									Ü			
Has FDA granted waiver/exc	eption/exemption for p	product?	No	If yes, attach docu	umentation from F	DA.		Box/Carton/Bundle/ Inner Pack:	5.82	14.02	3.94	7.13	393.852644	one E-Flute b		
			GTIN PRODUCT INFORMATION					Case:								
			Saleable						13.114	15.157	5.118	15.157	1175.78193	x, 2 E-Flute b		
			Level Unit		Linear		GTIN-14	Pallet:	Sea: 583.836	48	Sea: 40.83	40	#VALUE!	10 Vials in		
Serialized? If not, when?			Item X  Box/Carton/Bundle/Inner Pack	x 2D 2D 2D		10 50	10355150193308 30355150193302	UPC:	Air: 741.206 Case:	'503551501	Air: 51.06			Carton 5		
Items aggregated?			Case	2D 2D	Linear	100	50355150193306	llorc.	Carton:	1035515019						
X         Pallet         2D         Linear         4200         70355150193300           2D         Linear         Linear         Linear         Linear         Linear							Garton. 10000100100000									
						COST INFORMATION WHOLESALER USE ONLY:										
				2D	Linear											
	2D Linear				Regular Cost											
			2D Linear				Invoice Cost (WAC) (\$) \$1,430.00 Federal Excise Tax Per Unit of Sale			) Whsl. Code #: Fineline Code:						
							As of date:	2/9/2018		i ineline Coo						
											<u> </u>					
<u> </u>		At	tach copy of SAFETY DATA SHEET	(SDS) or non haza	ard letter, PACKAG	E INSERT, LAB	BEL AND PHOTO OF PRO	DUCT PACKAGING and B	ARCODE.							
*Please provide any addition	al information on pag	e 2.			See new p. 3 for	r Designated Di	rop 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 888-238-7880 Contact tel. # if product received damaged: CLASS OF TRADE RESTRICTION: Is product returnable for credit: Yes http://auromedics.com/policies/return-policy/ 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?						