

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014 Introduction Type: New Item					Fir	nal Version		Date:					
PRODUCT INFORMATION						SPECIAL HANDLING AND STORAGE REQUIREMENTS*							
Company Name: AuroMedics Pharma LLC ANDA				4	a. Temperature – Indicate the USP temperature range for this product.								
Application Number for			205867					F	Freezer – betwe	een -25 and -10	C (-13° – 14° F)	-	
DUNS:							ı		Cold – betweer	n 2 and 8 C (36°	° – 46° F)		
Rx Product/Proprietary N	ame:	DEXMEDETON	IDINE HYDROCHLORIDE	E INJECTION 20	00 mcg/ 2 mL (100 mcg/m	nL)				en 8 and 15 C (4	,		
NDC:	55150-209-02			UPC:	355150209026	,		x IV.	Controlled Ro	om – between 2	0 and 25 C (68°	– 77° F)	
CVX Code:				MVX Code:					allows for excu	ursions between	15 and 30 C (59	9° – 86° F)	
Description:	DEXMEDETOMIDINE	HYDROCHLOR	IDE INJECTION 200 mcg/	[/] 2 mL (100 mcg	/mL)			V.	Avoid Excessiv	ve Heat – above	e 40 C (>104° F)		
								VI.		rature Range Re	equirement		-
Active ingredients:									(write in)				
UDI for Additional Dradu		www.ouromodia						VII	I. No Requirem	ent			
URL for Additional Produ		www.auromedic	s.com										
Address:	6 Wheeling Road		State:	Address 2: NJ	Zip: 08	3810		b. Contact for t	emperature ex	xcursion quest	ions:		
City: Key Contact:	Dayton		Email:	NJ	Zip: 08	3810		Name: Number:					
Phone Number:	888-238-7880		Fax:	732-355-9449	9				t to be shipped	to customers or	n ice?		
		FOR	GENERIC DRUG PRODUC							to customers of			
		TOR											_
I. Orange Book Rating: III. Generic Equivalent for	AP		II. Brand Name:					c. Special regu	lations for pro	duct in cortain	ctatos?		
III. Generic Equivalent for													-
			IN SECURITY ACT (DSCS	SA) INFORMATI	ION			Special return	ns requirements	s for this product	ť?		_
Does supplier meet DSCS	SA definition of manu	facturer?	Yes										
Is product exempt from D	SCSA?	No	_			d. Store product (unit of sale) upright?							
If yes, select exemption	n:					Protect product (unit of sale) from light?							
Other exemption - Writ	e in:												_
Is product repackaged?													
is product repackageu:		No	If Yes, was origina	al product purc	hased direct from mfr?			e. Shelf life:		Months			
Is product sold by manufa		stributor?	If Yes, was origina			-		e. Shelf life:	Initial shelf lif	Months fe at launch (if o	different):		Months
		stributor? le?		If yes, attach	hased direct from mfr?			e. Shelf life:		fe at launch (if o			Months
Is product sold by manufa		stributor? le?	If Yes, was origina	If yes, attach		DA		e. Shelf life:					Months
Is product sold by manufa		stributor? le?	PRODUCT INFORMATION	If yes, attach I ORDER INFOR	documentation from FD	DA			ITEM AND	fe at launch (if o	ORMATION	Volume	<u>-</u>
Is product sold by manufi Are any waivers granted to Is the Product Legend Device?	for product ID/barcod	stributor? le? ADDITIONAL F	PRODUCT INFORMATION	If yes, attach ORDER INFOR What is the N	o documentation from FD RMATION NDC selling unit?	DA		e. Shelf life: Weight Lbs.	ITEM AND	fe at launch (if PACKING INFO	ORMATION	Volume (Cube)	Months
Is product sold by manufi Are any waivers granted to Is the Product Legend Device? State Control?	for product ID/barcod	stributor? ADDITIONAL F No No	Unit of Sale	If yes, attach I ORDER INFOR	o documentation from FD RMATION NDC selling unit?	DA	Item:		ITEM AND Dim	fe at launch (if PACKING INFO ensions (US ma	ORMATION smts.)		<u>-</u>
Is product sold by manufi Are any waivers granted to Is the Product Legend Device? State Control? ARCOS reportable?	for product ID/barcod	stributor? le? ADDITIONAL F 	Unit of Sale Bottle Bottle X Box/Carton	If yes, attach ORDER INFOR What is the N 25 Vials in on	a documentation from FD RMATION NDC selling unit? e Carton	DA		Weight Lbs.	ITEM AND Dim Depth	e at launch (if o PACKING INFO ensions (US ma Height	DRMATION smts.) Width:		# Pieces:
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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):						
a. Cytotoxic? No						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant? No						
Carcinogen						
Reproductive Toxicant						
Both						
Warning appears on label	Hazardous Waste Identification					
c. Contact Hazard?						
d. Does this product require special clean-up instructions?						
(If yes, attach SDS with special instructions.)						
e. Does the product contain DEHP?						
Is this product regulated for shipment by the DOT?	(if yes, answer a-d below and provide SDS)					
	a. DOT Hazard Class					
Is this a reportable quantity?	b. UN/ID Number					
RQ Threshold:	c. Packing Group					
Is this a marine pollutant?	d. Inhalation Hazard?					
Is this product shipped utilizing an authorized DOT exception or Special Permit?	G. milliouthfidzatu:					
(if yes, identify method below)						
Limited Quantity	ADDITIONAL PRODUCT INFORMATION - Serialization					
Consumer Commodity, ORM-D	Level How? GTIN-14					
Small Quantity (49 CFR 173.4)	Serialized? Item 2D Linear RFID 10355150209023					
Special Permit; DOT-SP	If not, when? Box/Carton 2D Linear RFID 10355150209023					
Special Provision (listed in Column 7 of 49 CFR 172.101);	Items aggregated to case? Case 2D Linear RFID 50355150209021					
SP#	Pallet 2D Linear RFID 70355150209025					
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS					
Passenger	Is there a REMS on this product?					
	If Yes, is it managed with a pharmacy registry? Website URL:					
Passenger & Cargo	Website UKL:					
ADD'L STORAGE INFORMATION	Comments / Details: (For example, iPledge program?)					
Please check as appropriate for this product.						
Organic Inorganic						
Antineoplastic Steroid/Androgen						
Corrosive Oxidizer						
Aerosol Class; Identify NFPA Storage Level:	RETURN INSTRUCTIONS					
Aerosol Class, Identily NEFA Storage Level.						
	Contact tel. # if product received damaged:					
	Is product returnable for credit:					
Listed Chemical (List I or II) (Indicate or Write-in below):	URL/Link to returns policy:					
Ephedrine	Special regulations or returns requirements for this product in certain states?					
Pseudoephedrine	If so, which states? Other requirements? Comments?					
Phenylpropanolamine						
lodine (≥2.2%)						
Other:						
CLASS OF TRADE RESTRICTION:	ADDITIONAL INFORMATION					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	If Unit Dose NDC, indicate NDC here:					
Restricted to retail pharmacy only:	MISCELLANEOUS NOTES and/or Image of Product Barcode:					
Restricted to hospital, clinics, and physician offices only:						
Restricted from US territories? (explain in comments)						
Comments:						



Standard Pharmaceutical Product Information (Page 3)

FOR DESIGNAT	ED DROP	SHIP PRODUCT	ONLY - if not a	designated	drop ship, d	o not con	nple	te.

Order Meth	hod for Designated Drop Ship Product	Standard Order Receipt and Processing			
Purchase orders may be accepted by: a. EDI b. Autofax	Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time:			
c. Fax	Fax Number:	Shipping lead time of PO: Hours Days			
d. Phone only	Phone No.:				
e. Supplier Web Site only	Site Address:	Ships same day for next day receipt:			
Minimum Order Quantity:		Ships for second day receipt:			
Supplier's Customer Service Number: Contracted 3PL company / contact #: Nar	mo	Ships regular ground for 3-10 days receipt:			
	one:	-			
	Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing			
	Charges of Other Designated Drop Ship Fees.				
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:		Days of week overnight is available: Monday			
Comments:		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 pharma	acy, hospitals, clinics and physician offices	Saturday Overnight receipt available:			
Restricted to retail pharmacy only:		PO Receipt Cut off time:			
Restricted to hospital, clinics, and physician office	es only:	Order receipt method: Phone: Phone #:			
Restricted from US territories? (explain in comme	ents)	Fax: Fax #:			
Comments:		EDI:			
		Overnight Fees apply:			
		Other fees apply:			
	REMS or Registry Restrictions	Return Instructions			
REMS:		Contact # if product is received damaged:			
REMS Program Manager Name:	Phone:	Is product returnable for credit:			
Supplier Manages REMS registry exclusiv Wholesale distributor support:		URL/Link to returns policy: Special regulations or returns requirements for this product in certain states?			
Provider Name:		If so, which states? Other requirements? Comments?			
Site Enrollment Number assigned	by Supplier:				
DEA #:		-			
PCPDP #:					
NPI #:					
Comments:		ADDITIONAL INFORMATION			
Registry:					
Registry Program Contact Name:	Phone:	Is product order for scheduled patient procedure?			
Comments		Is product order for restocking purposes?			
	a Information Required to Process PO:	Miscellaneous Notes:			
Patient Procedure Date:					
Physician Name:					
Physician/Clinic Phone #					
Physician State License # Physician/Clinic DEA #:					
Physician/Clinic DEA #.		111			