

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014			Intro	duction Type:	New Item		Fi	nal Version		Date:		
PRODUCT INFORMATION SPECIAL HANDLING AND STORAGE REQUIREMENTS*												
Company Name:	AuroMedics Pharma LL	LC			Application:		a. Temperature	e – Indicate the	e USP temperat	ture range for th	is product.	
	or NDA/ANDA/BLA, Med	Device:		Į	••		I	Freezer – betw	een -25 and -10	C (-13° – 14° F)		
Rx Product/Proprietary	Name:	SILDENAFIL IN	NJECTION 10 mg/12.5 mL	(0.8 mg/mL)				Cold – betwee	n 2 and 8 C (36°	′ – 46° F)		
NDC:	55150-166-13		0	UPC:	355150166138				en 8 and 15 C (4	,		
CVX Code:				MVX Code:			Yes IV	. Controlled Ro	om – between 2	0 and 25 C (68° ·	– 77° F)	
Description:	SILDENAFIL INJECTIO	ON 10 mg/12.5	mL (0.8 mg/mL)					allows for exc	ursions between	15 and 30 C (59	° – 86° F)	
									ve Heat – above	()		
Active ingredients:							VI		rature Range Re	equirement		1
URL for Additional Prod	uct Information:						(write in) VII. No Requirement					
Address:	6 Wheeling Road			Address 2:	[xcursion quest	ions:		
City:	Dayton		State:	NJ	Zip: 08810		Name:		Acuision quest	10115.		
Key Contact:			Email:	110			Number:	-				
Phone Number:	888-238-7880		Fax:	732-355-9449)		Is this produc	ct to be shipped	to customers o	n ice?	No	
		FOR	GENERIC DRUG PRODUC	стя			Is this produc	ct to be shipped	to customers of	n dry ice?	No	_
I. Orange Book Rating:	AP		II. Brand Name:	Revatio								_
III. Generic Equivalent fo							c. Special regu	ulations for pro	oduct in certain	states?	No	
	DRUG	SUPPLY CHA	AIN SECURITY ACT (DSCS	SA) INFORMAT	ION		Special return	ns requirement	s for this product	12	No	_
Does supplier meet DSC			Yes	DUNS:	968961354		opeoid return	no requirement				
Is product exempt from		No	165	Dono.	300301334		d. Store produ	unt (unit of col	a) unsight?		No	
		NO	_				•	•	,			_
If yes, select exemption Other exemption - Wr							Protect pro	duct (unit of s	ale) from light?	•	No	_
	L L L L L L L L L L L L L L L L L L L						.		1			
Is product repackaged?		No	If Yes, was origina	al product purc				24	Months			
Is product cold by many	facturar's avalusiva dia		_	a product pare	hased direct from mfr?		e. Shelf life:			difforant);		Months
Is product sold by manu Are any waivers granted		tributor?	No		-		e. Shen me.		fe at launch (if	different):		Months
Is product sold by manu Are any waivers granted	l for product ID/barcode	tributor?	No No	If yes, attach	documentation from FDA		e. Shen me.	Initial shelf li	fe at launch (if			Months
Are any waivers granted	l for product ID/barcode	tributor?	No	If yes, attach	- documentation from FDA		e. Shen me.	Initial shelf lin	fe at launch (if PACKING INF	ORMATION	Valuma	Months
Are any waivers granted	l for product ID/barcode	tributor? ? ADDITIONAL I	No No PRODUCT INFORMATION	If yes, attach ORDER INFOR	documentation from FDA		Weight Lbs.	Initial shelf linitial shelf linitial shelf linitial shelf linitial shelf linitian shelf linitia	fe at launch (if PACKING INF ensions (US ma	ORMATION smts.)	Volume (Cube)	Months
Are any waivers granted	l for product ID/barcode	tributor?	No No	If yes, attach ORDER INFOR	Adocumentation from FDA RMATION NDC selling unit?			Initial shelf lin	fe at launch (if PACKING INF	ORMATION	Volume (Cube)	-
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For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Carcinogen Reproductive Toxicant Both Warning appears on label 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?	Hazardous Waste Identification EPA Hazardous Waste Code:				
Is this product regulated for shipment by the DOT? 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)	(if yes, answer a-d below and provide SDS) a. DOT Hazard Class b. UN/ID Number c. Packing Group d. Inhalation Hazard?				
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#	ADDITIONAL PRODUCT INFORMATION - Serialization Level How? GTIN-14 Serialized? Item 2D Linear RFID If not, when? Box/Carton 2D Linear RFID Items aggregated to case? Case 2D Linear RFID Pallet 2D Linear RFID Incomparison				
Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo ADD'L STORAGE INFORMATION	REMS or REGISTRY RESTRICTIONS Is there a REMS on this product?				
Please check as appropriate for this product. Organic Inorganic Antineoplastic Steroid/Androgen Corrosive Oxidizer Aerosol Class; Identify NFPA Storage Level:	RETURN INSTRUCTIONS				
Listed Chemical (List I or II) (Indicate or Write-in below): Ephedrine Pseudoephedrine Phenylpropanolamine Iodine (≥2.2%) Other:	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?				
CLASS OF TRADE RESTRICTION:	ADDITIONAL INFORMATION				
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:	If Unit Dose NDC, indicate NDC here: MISCELLANEOUS NOTES and/or Image of Product Barcode:				



Standard Pharmaceutical Product Information (Page 3)

		FOR DESIGNATED	DROP SHIP	PRODUCT	ONLY - if n	ot a designated	l drop shir	o, do not	complete
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Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing				
Purchase orders may be accepted by:	Purchase order daily receipt cut off time by supplier				
a. EDI	Cut off time:				
b. Autofax Fax Number:					
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:	Ships regular ground for 3-10 days receipt:				
Contracted 3PL company / contact #: Name:					
Phone:]				
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:	Days of week overnight is available: Monday				
Comments:	Tuesday				
Comments.					
	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	Saturday Overnight receipt available:				
Restricted to retail pharmacy only:	PO Receipt Cut off time:				
Restricted to hospital, clinics, and physician offices only:	Order receipt method: Phone: Phone #:				
Restricted from US territories? (explain in comments)	Fax: Fax #:				
Comments:	EDI:				
	Overnight Fees apply:				
	Other fees apply:				
REMS or Registry Restrictions	Return Instructions				
	Construct # M and the second shared demonstration				
REMS:	Contact # if product is received damaged:				
REMS Program Manager Name: Phone:	Is product returnable for credit:				
Supplier Manages REMS registry exclusively:	URL/Link to returns policy:				
Wholesale distributor support:	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:					
Registry:	ADDITIONAL INFORMATION				
Registry Program Contact Name: Phone:	Is product order for scheduled patient procedure?				
Comments	Is product order for restocking purposes?				
Other Data Information Required to Process PO:	Miscellaneous Notes:				
Patient Procedure Date:					
Physician Name:					
Physician/Clinic Phone #					
Physician State License #					
Physician/Clinic DEA #:					
Physician/Clinic Specialty:					