

Standard Pharmaceutical Product Information (Rx Product Only)

					intr	roduction Type) :	New Item	<u> </u>	Final Version			Date:	5/1/.	2019
			PRODUCT INFORMATION	N						SPECIAL HANDL	ING AND ST	ORAGE REQ	UIREMENTS	S*	
Company Name: Application Number for NDA	AuroMedics Pharma LLC	10(k)(med device):		210965		Applicat	tion:	ANDA		ndicate the USP temper	ature range			een 20 and 25	C (68° – 77° F
DUNS:	968961354			2.0000					-	=					- (
Proprietary Name (If Applicate		Progestero	one Injection, USP 500 mg/10	ml (50 mg/ml) (MD\/)	1				Othe	r Temperature Range Re (write in)	equirement				1
Selling Unit NDC:	55150-306-10	Flogestero	Individual Unit NDC:	55150-306-		UPC: 355	5150306107	7	-	(write iii)					1
UDI	00100 000 10		CVX Code:	00.000.000		X Code:	0100000101		Is this	s product to be shipped t	to customers	on ice?		No	
Description:	Progesterone Injection, USP	500 mg/10mL (50 m							= 1	s product to be shipped t				No	-
Active Ingredient(s):	Proge	esterone								perature excursion ques	stions:	Ctava Lucas			
URL for Additional Product In	nta-matian.	auromedics.com							Name Num			Steve Lucas 888-238-788			
Address:	279 Princeton-Hightstown Ro				Address	e 2·				ip E-mail:			indousa.com		
City:	East Windsor	ouu		State:		Zip:	0	08520	Giod	ip L-man.		progeautobi	indousa.com		
Key Contact:				Email:					c. Special regulation	ons for product in any s	tates?			No	
Phone Number:	888-238-7880			Fax:	732-355	5-9449				cial returns requirements		uct?		No	-
Product Therapeutic Classific	cation: Hormo	onal Agent; Progestir	n						_	•					_
									d. Store product (u	nit of sale) upright?				No	_
ADDITIONAL	L PRODUCT INFORMATION				PRODUCT	T DESCRIPTIO	N INFORMA	ATION	Prote	ect product (unit of sale	e) from light?	?		No	_
Is the Product									e. Shelf life:					24	Months
a legend device?		No		Size:		1 x 1 Vial			Initia	al shelf life at launch (if	different):				Months
reverse numbered?		No		Size.		I X I VIAI									
co-licensed?		No		Strength:		500 mg/10mL	(50 ma/mL)			C	ORDER INFO	RMATION			
Is the Product	Direct	-Ship Only					,		!			140	NDO III		
Is the Product				Dosage Fo	orm:	Liquid			Unit	of Sale Bottle		1 box of 1 vi	NDC selling	j unit?	
									J x				g. 1 Box of 1	0 Vials)	
If Unit Dose, is item bar coded	d to unit dose for hospital sca	nning?							լ 	Ampule		(vviite iii, c.	.g. 1 Dox 01 1	o viais)	
If Unit Dose NDC, indicate NE	DC here:			Product Sh	hape:					Glass		Minimum o	rder quantity	y?	Yes
				Product Co	olor:					Tube					
Country of Origin	India				0.0					Vial Liquid Sgl					
Is this product covered under	the Trade Agreements Act (T	AA)?		Product Im	nprint:					Vial Liquid Multi				ich package t	type?
		No No							JII —	Vial Powder Sql			Each	/Pook	
		NO							<u> </u>	Vial Power Multi			Inner/Cartor	n/Pack	
			FOR GENERIC DRUG PROD	UCTS							7			n/Pack	
			FOR GENERIC DRUG PROD	UCTS						Vial Power Multi Other: Write In			Inner/Cartor Case	n/Pack	
			FOR GENERIC DRUG PROD		uthorized Ger			Generic, other section		Vial Power Multi Other: Write In	RMACY ORDI	ER / BILL UN	Inner/Cartor Case	n/Pack	
I. Orange Book Rating:	AP	F	FOR GENERIC DRUG PROD				Authorized (Rec. sell unit to cus	Vial Power Multi Other: Write In PHAR stomer?	RMACY ORDI	ER / BILL UN	Inner/Cartor Case		
I. Orange Book Rating: II. Generic Equivalent to What			FOR GENERIC DRUG PROD						1 Mono vial	Vial Power Multi Other: Write In PHAR stomer? in 1 Mono carton	RMACY ORD	ER / BILL UN	Inner/Cartor Case T nit to pharm Each		
		F sterone Injection		A	uthorized Ger					Vial Power Multi Other: Write In PHAR stomer? in 1 Mono carton	RMACY ORDI	ER / BILL UN	Inner/Cartor Case T nit to pharm Each Gram		
		F sterone Injection	FOR GENERIC DRUG PROD	A	uthorized Ger				1 Mono vial	Vial Power Multi Other: Write In PHAR stomer? in 1 Mono carton	RMACY ORDI	ER / BILL UN	Inner/Cartor Case T nit to pharm Each		
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II. Generic Equivalent to What Does supplier meet DSCSA d Is product exempt from DSCS If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufactu Has FDA granted waiver/exce	definition of manufacturer? SA? urer's exclusive distributor? eption/exemption for product	DRUG SUPPLY No No No No No No No No No N	CHAIN SECURITY ACT (DS Yes O No No STIN PRODUCT INFORMA Level Lewel Lewel Lewel Lox/Carton/Bundle/Inner Pack Case	GLN: If Yes, was originated from mfr? If yes, attach definit If Yes, was originated from mfr? If yes, attach definit 20 21 22 22 22 22 22 22 22 22 22 22 22 22	uthorized Ger	ct purchased di on from FDA. Linear in. Linear on. Linear on. Linear per Linear Linear Linear Linear Linear Linear Linear Linear	irect	GTIN-14 0356150306107 10355150306108 0355150306106 0355150306106	Item: Box/Carton/Bundle Inner Pack: Case: Pallet: UPC: Regular Cost Invoice Cost (WAC) Federal Excise Tax As of date:	Vial Power Multi Other: Write In PHAR stomer? in 1 Mono carton I) ITEM A Weight Lbs. 0.11 1.536 10.428 867.263 Case: Carton: OST INFORMATION I) (\$) (Per Unit of Sale 5/1/2019	Dime Depth 1.57 6.73 12.008 48 503551503	Rx billing u x S INFORMAT ensions (US m Height 3.07 3.78 12.795 56.97 Vendor #: Whsl. Code	Inner/Cartor Case IT nit to pharm Each Gram Milliliter ION Inserts.) Width 1.5 5.5 7.677 40 WHOLESAL	Volume (Cube) 7.22985 139.9167 1179.5124 109382.4	1 vial 12 72 5760



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. Cvtotoxic? 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? Oxidizer No Inorganic 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? No If Yes, is it managed with a pharmacy registry? Cargo 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: Special Provision (listed in Column 7 of 49 CFR 172.101); Site Enrollment Number assigned 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: Phone Schedule No. (inc. N for non-narcotic) Comments Controlled Substance Code RETURN INSTRUCTIONS Listed Chemical (List I or II) No If yes, indicate which: 888-238-7880 Is it a scheduled listed chemical product?: No Contact tel. # if product received damaged: CLASS OF TRADE RESTRICTION: Is product returnable for credit: Yes URL/Link to returns policy: http://auromedics.com/policies/return-policy/ No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments? Restricted to hospital, clinics, and physician offices only: 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 b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone: Expedited Freight Charges or Other Designated Drop Ship Fees:	Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt: 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 Wednesday Thursday Friday
	Priority Overnight receipt available:
Class of Trade Restriction: 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:	PO Receipt Cut off time: 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: Miscellaneous Notes:	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?
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure? Is product order for restocking purposes?