

Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Page	Version 2021						Introduction T	ype: New Item	n		Final Version			Date:	5/29/2	:024
Application believe for NOAMONEAN ARRAY PROPERTY STORES (1987 1976) 1976				PRODUCT INFORMA	TION						SPECIAL HA	ANDLING AND ST	ORAGE REC	UIREMENT	S*	
Application Number for NOAM-NEAM-Applicate Application Number for NOAM-Applicate Application	Company Name:	Novadoz Pharma	aceuticals LLC				Applicat	tion: ANDA	١	a. Temperature – Indicate the USP temperature range for this product.						
Display Disp	Application Number for NDA/AN			device):	217	7521									8° – 77° F)	
Popularity Name Application year Application																
March Marc												Requirement				
Control Cont			lame: Ph		tion, USP 100 r	ng/10 mL (10 r					rite in)					
Contact Cont		72205-266-07						372205266070		Notes						
Active largeridamenty:							IWIVA Code.									
Address Distant Contact for temporary Product State	Description:	Clear colorless s	olution, free from	visible particulate matter												_
Content for registerable recording registers Product Interception Classifications Product Interception Classification Cl	Active Ingredient(s):		Phenylephrine I	Hydrochloride						is this pi	roduct to be snipper	u to customers on	i di y ice :		140	
Marie Mari			,,	.,,						b. Contact for tempera	ature excursion qu	estions:				
State Stat			www.novado	ozpharma.com						Name:	•					
Report Part																
Product Throughout Classification Aprox 1 attrough response agricult Product Throughout Classification Aprox 1 attrough response agricult Product Throughout Classification Aprox 1 attrough response agricult Product Through divisors Aprox 1 attrough divisors Security		Piscataway								Group E-mail: chrao.t@msnlabs.com						
Product Classification: April - Enteroperation April - Enteropera		908-360-1500								c Special regulations	for product in any	states?			No	
ADDITIONAL PRODUCT BY COMMATION The product is? In the product is? In September 1			Alpha-1 adrene	raic recentor agonist		l ux.	732-302-2113						2			
The product is? Is the Product Nombral If she product Nombral If	Troduct Therapeutic Glassification	JII.	/ upria i adierie	igic receptor agoriist		1				Орсска	returns requirement	is for this product			140	
The product is 7 is the Product Neither Option Right? If yes, list NOS of component parts preservate free? If yes, list NOS of component parts preservate free? If yes, list NOS of component parts preservate free? It yes, list NOS of component parts preservate free? It yes, list NOS of component parts preservate free? It yes, list NOS of component parts preservate free? It yes, list NOS of component parts preservate free? It yes, list NOS of component parts preservate free? It yes, list NOS of component parts preservate free? It yes, list NOS of component parts preservate free? It yes, list NOS of component parts preservate free? It yes, list NOS of component parts preservate free? It yes, list NOS of component parts preservate free? It yes, list NOS of the prese		ADDITI	ONAL PRODUCT	T INFORMATION			PRODUCT D	DESCRIPTION INFORMA	TION	d. Store product (unit	of sale) upright?				Yes	7
a linguist device? State Product	The product is?				Direct-Shin C	Only						ale) from light?				i
Fig. 2 Section Feed Fe							Cinc.	10ml			F 2401 (41111 01 30	,				Months
# Systation Does a Component parts							Size:			Initial sl	helf life at launch (if different):				Months
Sheet Number of State Product Shape:							Strength:	100mg/10mL (10	mg/mL)							
reverse numbered? Intex-fee? Inte				FDA Approval Status				0.1.1				ORDER INFO	DRMATION			
Collegated Product Color: Product Shape: Product Imprint: If unit Date, is sen har coded to unit does for hospital scanning? If unit Date, is sen har coded to unit does for hospital scanning? If unit Date, is sen har coded to unit does for hospital scanning? If unit Date, is sen har coded to unit does for hospital scanning? If unit Date, is sen har coded to unit does for hospital scanning? If unit Date, is sen har coded to unit does for hospital scanning? If unit Date, is sen har coded to unit does for hospital scanning? If unit Date, is sen har coded to unit does for hospital scanning? If unit Date, is sen har coded to unit does for hospital scanning? If unit Date, is sen har coded to unit does for hospital scanning? If unit Date, is sen har coded to unit does for hospital scanning? If unit Date, is sen har coded to unit does for hospital scanning? If unit Date, is sen har coded to unit does for hospital scanning? If unit Date, is sen har coded to unit does for hospital scanning? If unit Date, is sen har coded to unit does for hospital scanning? If unit Date, is sen har coded to unit does for hospital scanning? If unit Date, is sen har coded to unit does for hospital scanning? If unit Date, is sen har coded to unit does for hospital scanning? If unit Date, is sen har coded to unit does for hospital scanning? If unit Date, is sen har coded to unit does for hospital scanning with the product part of the part of the product part of the part of the product part o							Dosage Forn	n: Solution		Unit of	Sala		What is the	NDC salling	unit?	
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preservative-free? Ves Correctional institution block? Correctional institution block? Common block in the product Color: Product Imprint: If yes, how many of which package type? If unit Does, is from his code for incident NDC here: If unit Does, indicate NDC here: Today Book Rating: If yes, product personal institution block? Authorized Generic: If Au							Broduct Sho	N/A		x					10 Vials)	
opioid? Cannabinoid? If Unit Dose, it after be product covered under the roughl scanning? If Unit Dose, it after be roughly a committed of the roughly and the	preservative-free?		Yes				Froduct Sila	pe.			Ampule					
County of Origin County							Product Cold	Clear colorless					Minimum o	rder quantit	y?	Yes
If Unit Dose, is discaled found dose for hospital stamping? If Unit Dose, indicate NDC here: It Unit Dose, indicate NDC here: It Date Agreements Act (TAA)? No				0												
Lorange Book Rating:		unit does for	NO	Country of Origin			Product Imp	rint: N/A					If Yes how	many of wh	ich nackage type	۵2
It livit Dose, indicate NDC here: Trade Agreements Act (TAA)? No		unit dose for		Is this product covered u	inder the						- '		1		non package type	٠.
Authorized Generic, Other section fields are not applicable II. Generic Equivalent to What Brand?: Authorized Generic Section fields are not applicable Section fields are not applicable Section fields are not applicable			72205-266-07			No									n/Pack	
Authorized Generic Other section fields are not applicable I. Generic Equivalent to What Brand? DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION Does supplier meet DSCSA definition of manufacturer? Yes											Other: Write In			Case		
Corange Book Rating: AP2				FOR GENERIC DRUG PR	ODUCTS											
Corange Book Rating: AP2												NIA DIMA OV ODE	ED (BILL LIN	UT		
Continue					_	Au	ithorized Generic					PHARMACY ORL				
Write-in, e.g. 1 Vial) Write-in, e.g. 1 Vi								occion noido dio not app	piloubio			1	Rx billing u		nacy:	
Does supplier meet DSCSA definition of manufacturer? Yes If yes, select exemption: Other exemption: Other exemption Write in: Is product expectated? If yes, select exemption: Other exemption of product? No No If yes, was original product packaged? If yes, was original product purchased direct from mfr? Provide source manufacturer for repackaged product If yes, attach documentation from FDA. Saleable Unit of Measure Yes Saleable Unit of Measur	II. Generic Equivalent to what Bra	and ::									ı	J				
Does supplier meet DSCSA definition of manufacturer? Yes Supplier meet DSCSA? No Supplier meet DSCSA? No Supplier meet DSCSA? No Supplier meet DSCSA? Supplier meet DSCSA? No Supplier meet DSCSA? Supplier meet DSCSA? Supplier meet DSCSA? No Supplier meet DSCSA? Supplier meet DSCSA. Sup			DRUG SUF	PPLY CHAIN SECURITY ACT (DSCSA) INFOR	RMATION				(vviite iii, e.g. 1 viai)						
Is product exempt from DSCSA? If yes, select exemption: Other exemption: Other exemption: Other exemption white in: Is product old by manufacturer's exclusive distributor? No Has FDA granted waiver/exception/exemption for product? No CIN AND HIBCC PRODUCT INFORMATION Weight Lbs. Objects Weight Lbs. Objects Weight Lbs. Objects				·										-		
If yes, select exemption: Other exemption: Other exemption - Write in: Sproduct repackaged? No If yes, was original product purchased direct from mfr? No Provide source manufacturer for repackaged product No Provide source manufacturer			urer?			GLN:	8904159670843				ITE	EM AND PACKIN	G INFORMAT	ION		
Other exemption - Write in: Is product repackaged? If yes, was original product purchased direct from mft? Has FDA granted waiver/exception/exemption for product? If yes, attach documentation from FDA. If yes, was original product purchased direct from mft? Provide source manufacturer for repackaged product Saleable Unit of Measure	· ·			INO												
Sproduct repeakaged? No If yes, was original product Sproduct sold by manufacturer's exclusive distributor? No Provide source manufacturer for repackaged product Provide source manufacturer for repackaged product Provide source manufacturer for repackaged product Saleable Unit of Measure Saleable Quantity Yes Item/Each 1 Carton Pack 4 Cartons in Outer pack 4 Cartons in Outer pack 2 Cartons in pallet 50372205266075 S0372205266075 S0372205266						GCP:	89041596				Weight Lbs.			-	Volume (Cube)	
Saleable Unit of Measure Saleable Quantity Yes Rem/Each Cartons in Oase 24 Cartons in Case 25 Carton				No		If you was a	riginal product			Itom/Each:	1			1	1	Pieces
Has FDA granted waiver/exception/exemption for product? If yes, attach documentation from FDA. Provide source manufacturer for repackaged product		s exclusive distrib	outor?		-					iciii/Lacii.	0.509	5.11	2.04	2.55	26.58	1
Saleable Unit of Measure Saleable Quantity HIBCC GTIN-14 Unit of Use GTIN-14 O3772205266070 Yes Nem/Each 1 Carton Pack 2 Cartons in Quiter pack 4 Cartons in Quiter pack 2 Cartons in pallet S0372205266074 S0372205266075 S0372205266075 S0372205266076 S03722052660						•		or repackaged product		Box/Carton/Bundle/	2 260	10.00	152	3 1 4	152 56	4
Saleable Unit of Measure Saleable Quantity 1 Carton Pack Yes Item/Each Y	If yes, attach documentation fro	om FDA.									2.300	10.62	4.52	3.14	155.50	4
Saleable Unit of Measure Saleable Quantity Teach Saleable Quantity 1 Carton Pack 4 Cartons in Outer pack Yes BowCarton/Bundle/Inner Pack 4 Cartons in Case 960 Cartons in pallet Source So				OTIN AND LUDGO BRODUCT U	JEODMATION.					Case:	15.20	15.35	11.81	7.87	1,426.70	24
Saleable Unit of Measure Yes Item/Each Yes Oxage Yes Pallet 960 Cartons in pallet Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE. Value			(GTIN AND HIBCC PRODUCT II	NFORMATION					Dellet			-		•	
Yes	Saleable Unit of Measure		Saleable Quantity	HIBCC		GTI	N-14	Unit of Use GTIN	N-14	Pallet:	647.84	47.24	39.37	37.4	69,557.97	960
Yes		`		TIDOO							<u> </u>	1	1	1	1	-
Yes Pallet 960 Cartons in pallet 50372205266075 Regular Cost Invoice Cost (WAC) (\$) \$100.00 Whsl. Code #: Fineline Code: Fin	Yes Box/Carton/Bundle/Inner Pack	4 C	artons in Outer pa	ack		203	72205266074			COS	T INFORMATION			WHOLES	ALER USE ONLY	' :
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE. Invoice Cost (WAC) (\$) \$100.00 Whsl. Code #: Fineline Code:																
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.	Yes Pallet	96	0 Cartons in palle	t		503	72205266075	-						м.		
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.		_						-		invoice Cost (WAC) (\$)	\$100.00				
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.		-						-		As of date:	5/29/2024		I memie Co	uc.		
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								_								
				Attach copy of SAFETY D	ATA SHEET (S	SDS) or non ha				F PRODUCT PACKAGING	and BARCODE.					



Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

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For Designated Drop Ship Only Products, Please Use Page 3

MA	TERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant?	SDS Hazard Classification Organic Corrosive Inorganic Oxidizer						
Does the product label bear a CA Prop 65 warning?	No No	Steroid/Androgen	Contact Hazard				
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?	No No	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level:	No				
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name	No	Is the product a NIOSH hazardous drug? If yes, indicate which:	No				
c. DOT Hazard Class		Hazardous Waste Identification					
d. Packing Group e. Inhalation Hazard?	No	EPA Hazardous Waste Code:		Waste Characteristics			
		EFA Hazaidous Wasie Code.		Waste Characteristics			
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)	No	REMS o	r REGISTRY RESTRICTIONS				
a. UN/Identification Number							
b. Proper Shipping Name		Is there a REMS on this product?	No				
c. DOT Hazard Class d. Packing Group		If Yes, is it managed with a pharmacy registry? Website URL:					
e. Inhalation Hazard?	No	Website OILE.					
Is the product restricted for air shipment? If so, indicate restriction:	No	Med Guide Required	No				
Passenger		Limited Distribution Requirement	No				
Cargo		Comments / Details: (For example, iPledge program?)					
Passenger & Cargo		DEMO.	NI-				
Is this a reportable quantity? No RQ Threshold:		REMS Program Manager Name:	No	Phone:			
Is this a marine pollutant?		Supplier Manages REMS registry exclusively:		. Holler			
Is this product shipped utilizing an authorized DOT exception or Special Permit?		Wholesale distributor support:					
No (if yes, identify method below) Limited Quantity		Provider Name: Site Enrollment Number assigned		DEA #: NCPDP#:			
Consumer Commodity, ORM-D		by Supplier:		NPI #:			
Small Quantity (49 CFR 173.4)							
Special Permit; DOT-SP		Comments					
Special Provision (listed in Column 7 of 49 CFR 172.101); SP#		Pariety:	No				
3F#		Registry: Registry Program Contact Name:	INO	Phone:			
ADD'L STORAGE INFORMATION		Comments					
Is the Product							
Controlled Substance? No Controlled Substance Code		R	ETURN INSTRUCTIONS				
Controlled by State(s)? No Listed Chemical (List I or II) ARCOS Reportable? No If yes, indicate which:	No	Contact tol. # if and just received demonstrat					
Schedule No. Is it a scheduled listed chemical product?:	No	Contact tel. # if product received damaged:					
CLASS OF TRADE RESTRICTION:		Is product returnable for credit: URL/Link to returns policy:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Yes	Cita zinik to rotamo ponoji					
Restricted to retail pharmacy only:	No	Charles and standard and standard and standard from the					
	No	Special regulations or returns requirements for this product in certain states?	No				
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)	No	If so, which states? Other requirements? Comments?	INU				
Comments:							
	SCELLANEC	DUS NOTES and/or Image of Product Barcode:					



Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop S	nip 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 c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	per:	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:
Expedited Freight Charges or Other Designa	ed Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order:		Overnight receipt available: 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, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	s and physician offices	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to F	rocess 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?