

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

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Version 2021						Introduction Type	pe: New Item		x Final Version			Date:	7/22/	/2025
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STO	RAGE REQUI	REMENTS*		
Company Name:	Novadoz Pharmad	ceuticals, LLC				Applicatio	on: ANDA	a. Temperatu	ure - Indicate the USP tempe	erature range for t	his product.			
Application Number for NDA/AN	DA/BLA (drug); PN	/IA/510(k)(med o	levice):	21:	3748		'		Temperature Range	Controlled Room		and 25 C (68	s° – 77° F)	
Medical Device Class, if applicat	ble:				_									
DUNS:	081109687								Other Temperature Range	Requirement	NA			
Proprietary Name (If Applicable) a	nd Established Na	ime: S	acubitril and Valsartan Tablets 9	′ mg/103 mg, 18	80				(write in)					
Selling Unit NDC: UDI	72205-282-18		Unit of Use NDC: CVX Code:			UPC: 3	372205282186		Notes		NA			
							1 14 1661							1
Description:	Light pink to pink (Colored, oval sh	aped, biconvex, film coated table	ts one side deb	ossed with 'M' a	and other side deboss	sed with 'S3'.		Is this product to be shipped Is this product to be shipped				No No	
Active Ingredient(s):		Sacubitril And	/alsartan						is this product to be shipper	a to customers on	ary ice:		INU	
								b. Contact fo	r temperature excursion qu	estions:				
URL for Additional Product Inform	nation:								Name:					
Address:	20 Duke Road						Suite A		Number:					
City:	Piscataway				State: Email:		Zip: 08854		Group E-mail:					
Key Contact: Phone Number:	908-360-1500				Fax:	732-902-2113	s@novadozpharma.com 902-2113 c. Special regulations for product in any states?			states?			No	1
Product Therapeutic Classification					ı ax.	732-902-2113		C. Special re	Special returns requirement				No	
Product Therapeutic Glassification					1				opeciai returns requiremen	is for this product:			140	
	ADDITIO	ONAL PRODUC	T INFORMATION			PRODUCT DE	ESCRIPTION INFORMATION	d. Store prod	duct (unit of sale) upright?				Yes	1
The product is?			Is the Product	Direct-Ship C	nly				Protect product (unit of sa	ale) from light?			Yes	1
a legend device?		No	Is the Product	Neither	,	0:	180	e. Shelf life:	r rotoot product (dim or or	,g			48	Months
if yes, enter class #			Orphan Drug Status			Size:			Initial shelf life at launch (if different):			36	Months
a product kit?		No				Strength:	97 mg/103 mg							
if yes, list NDCs of			FDA Approval Status							ORDER INFORI	MATION			
component parts reverse numbered?						Dosage Form:	Tablet		Unit of Sale		What is the	NDC calling	unit?	
co-licensed?			Allergens Present						x Bottle		1 bottle of 1		unit:	
latex-free?		Yes	7 morgono i roconi				Oval shaped		Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		Yes				Product Shape	e: '		Ampule			•	,	
correctional institution block?						Product Color:	Light Pink to Pink Color	ed	Glass		Minimum or	der quantity	?	Yes
opioid?									Tube					
Cannabinoid?			Country of Origin			Product Imprir	nt: one side debossed with	'M'	Vial Liquid Sgl		W. V 1			
If Unit Dose, is item bar coded to un hospital scanning?	ınıt dose for		Is this product covered u	nder the					Vial Liquid Multi Vial Powder Sql			Each	ch package	type?
If Unit Dose, indicate NDC here:		72205-282-18	Trade Agreements Act (No				Vial Power Multi		40	Inner/Cartor	/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
											_			
					Αι		*If Authorized Generic, other		Ph	IARMACY ORDER	/ BILL UNIT			
	AB					S	section fields are not applicabl	Rec. sell uni	t to customer?	_	Rx billing u		асу:	
II. Generic Equivalent to What Bra	nd?:	Entresto									X	Each		
		DBIIC SI	IPPLY CHAIN SECURITY ACT	Decea) INFO	MATION			(Write-in, e.g	ı. 1 Vial)			Gram Milliliter		
		DRUG 30	THE CHAIN SECONT FACT	DOCOA) IN OF	MATION							williller		
Does supplier meet DSCSA definit	tion of manufacture	er?	Yes		GLN:	8904159670843			ITEN	I AND PACKING I	NFORMATIO	١		
Is product exempt from DSCSA?			No											
If yes, select exemption:					GCP:	89041596				Dimens	ions (US msn	nts.)	Volume	Saleable #
Other exemption - Write in:									Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			riginal product purch	nased	Item/Each:	0.26	NA	2.218	4.62	175.00	1
Is product sold by manufacturer's			No No		direct from n									
Has FDA granted waiver/exception If yes, attach documentation from		oduct?	NO		Provide sour	ce manufacturer for I	repackaged product	Box/Carton/i	Bundle/ NA	NA	NA	NA	NA	NA
ii yes, attacii documentation iroi	III FDA.							Case:			1			
			GTIN AND HIBCC PRODUCT I	NFORMATION				Ousc.	13.52	14.37	9.84	10.63	1503.09	48
								Pallet:	526.4	47.24	39.37	37.79	70,283.31	1,728
Saleable Unit of Measure		aleable Quantity				N-14	Unit of Use GTIN-14		320.4	47.24	33.37	31.13	70,200.01	1,720
Yes Item/Each	1 Bo	ottle of 180 Tabl	ets			72205282186	00372205282186		COST INFORMA TION			WILOU ECAL	ED LIGE ONL	V
NA Box/Carton/Bundle/Inner Pack	46	NA B Bottles in Case			NA 303	72205282187			COST INFORMATION			WHOLESAL	ER USE ONL	.1:
Yes Case Yes Pallet		28 Bottles in Case				72205282181		Regular Cos	•		Vendor #:			
1.50 1 and	1,72	Lo Dottico III I al						Invoice Cost		\$1,250.00		#:		
					1						Fineline Co			
								As of date:	7/22/2025					
								As of date:	7/22/2025					
			Allech and (CAFFT)	TA OUEST (25		DAOWACE TO	NICEDT LADEL AND DUCTO							
*Please provide any additional info	ormation on page (2	Attach copy of SAFETY Da	ATA SHEET (SC	S) or non haza		NSERT, LABEL AND PHOTO Designated Drop Ship 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				
	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)	If so, which states? Other requirements? Comments?	INU				
Comments:	No					
	SCELLANEC	DUS NOTES and/or Image of Product Barcode:				
			<u> </u>			



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

Order Method fo	r 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 c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity:	Fax Number: Fax Number: Phone No.: Site Address:	Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt:				
F	Name: Phone:	Ships regular ground for 3-10 days receipt:				
Expedited Freight Charg	ges 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 only: Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician of Restricted from US territories? (explain in conficulty) Comments:	offices only:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:				
Other Data Infor	rmation 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?				
Mis	scellaneous Notes:					
		ADDITIONAL INFORMATION				
		Is product order for scheduled patient procedure? Is product order for restocking purposes?				