

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

Version 2024						Introduction Type	: New Item	x	Final Version			Date:	11/25	5/2025	
			PRODUCT INFORMA	TION					SPECIAL HAN	IDLING AND STOR	AGE REQUI	REMENTS*			
Company Name: Novadoz Pharmaceuticals, LLC Applica						Application	: ANDA	a. Temperature – Inc	a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/AN	IDA/BLA; PMA/51	0(k):	218178			NDA 505(b) Type:		Temp	erature Range	Controlled Room	- between 20	and 25 C (68	° – 77° F)		
Medical Device Class, if applica					_										
DUNS:	081109687								Temperature Range I	Requirement					
Proprietary Name (If Applicable) a	72205-222-30	lame:	Perampanel Tablets 4 mg, 30 Unit of Use NDC:			UPC: 37	2205222304		(write in)						
Selling Unit NDC: UDI	72203-222-30		CVX Code:			MVX Code:	2205222304	Notes							
Description:	Davana and Tak	lata 4 may ana Du	ick red colored, round shaped, bice	amilai film aaaf			da and "00" an ather side	la shia	product to be shipped	d toto	2		No	1	
Description:	Perampaner rab	nets 4 mg are bi	ick red colored, round snaped, bick	onvex, ilim-coal	ed labiets, deb	ossed with P on one si	de and 22 on other side.		product to be shipped				No		
Active Ingredient(s):									product to be emppe	a to outsimore on a	.,		110	l.	
l	_							b. Contact for tempe		estions:					
URL for Additional Product Inform Address:	nation: 20 Duke Road				1	Address 2: Su	11 - A	Name							
City:	Piscataway				Address 2: Suite A State: NJ Zip: 08854			Numb	er: o E-mail:						
Key Contact:	1 loodiamay				Email:	sales@novadozph		- Group E maii.							
Phone Number:	908-360-1500				Fax:	732-902-2113	32-902-2113		c. Special regulations for product in any states?						
Product Therapeutic Classification	on:							Specia	al returns requirement	ts for this product?					
								_							
	ADDIT	TIONAL PRODU	CT INFORMATION			PRODUCT DES	CRIPTION INFORMATION	d. Store product (un	it of sale) upright?						
The product is?			Is the Product	Direct-Ship C	Only				ct product (unit of sa	ale) from light?					
a legend device?		No	Is the Product	Neither		Size:	30	e. Shelf life:					24	Months	
if yes, enter class #		lat.	Orphan Drug Status				4	Initial	shelf life at launch (if different):				Months	
a product kit? if yes, list NDCs of		No	FDA Approval Status			Strength:	4 mg			ORDER INFORM	MATION				
component parts			1 DA Approvar Status				Tablets			5115 <u>211 1111 51111</u>	.,				
reverse numbered?		No				Dosage Form:		Unit o	f Sale		What is the	NDC selling	unit?		
co-licensed?		No	Allergens Present					Х			1 bottle of 3				
latex-free?		Yes				Product Shape:	Round		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)		
preservative-free? correctional institution block?		Yes					Brick red		Ampule Glass		Minimum o	rder quantity		Yes	
opioid?		No No				Product Color:	Blick red		Tube		winimum o	rder quantity	r	res	
Cannabinoid?		No	Country of Origin				"P" on one side and "22"		Vial Liquid Sql						
If Unit Dose, is item bar coded to	unit dose for		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			Product Imprint	on other side		Vial Liquid Multi		If Yes, how	many of whi	ch package	type?	
hospital scanning?			Is this product covered u						Vial Powder Sql		48	Each			
If Unit Dose, indicate NDC here:		72205-222-30	Trade Agreements Act (ΓAA)?	No				Vial Power Multi			Inner/Carton	/Pack		
				AD11070					Other: Write In			Case			
			FOR GENERIC DRUG PR	ODUCIS											
					Au	uthorized Generic *If	Authorized Generic, other		PH	ARMACY ORDER	/ BILL UNIT				
I. Orange Book Rating:	AB				section fields are not applicable			Rec. sell unit to customer? Rx billing unit to pharmacy:							
II. Generic Equivalent to What Brand?: Fycompa							Each								
-							(Write-in, e.g. 1 Vial)		_		Gram				
		DRUG S	SUPPLY CHAIN SECURITY ACT (DSCSA) INFO	RMATION			HCPCS J-Code:				Milliliter			
Does supplier meet DSCSA defin	ition of manufactu	ırer?	Yes		GLN:	8904159670843			ITEN	AND PACKING I	NEORMATIO	N			
Is product exempt from DSCSA?	nion or manaracte	arci .	No	-	OLIV.	0304103070043									
If yes, select exemption:					GCP:	89041596		i		Dimensi	ons (US msr	nts.)	Volume	Saleable #	
Other exemption - Write in:						00011000		1	Weight Lbs.	Depth	Width	Height	(Cube)	Pieces	
Is product repackaged?			No		If yes, was o	riginal product purcha	sed	Item/Each:	0.079	NA	1.53	3.28	54	1	
Is product sold by manufacturer's			No		direct from n				0.073	107	1.00	0.20	0-1		
Has FDA granted waiver/exception If yes, attach documentation fro		product?	No		Provide sour	ce manufacturer for re	packaged product	Box/Carton/Bundle/ Inner Pack:	NA	NA	NA	NA	NA	NA	
ir yes, attach documentation fro	m FDA.							Case:							
			GTIN AND HIBCC PRODUCT II	NFORMATION				I Gasc.	4.708	10.43	7.28	7.67	582.39	48	
								Pallet:	472.81	47.24	39.37	36.61	68089	4,416	
Saleable Unit of Measure	RFID tag(Y/N)		HIBCC		GT	IN-14	Unit of Use GTIN-14		472.01	47.24	33.37	30.01	00003	4,410	
	4.5	Quantity				7700500004	000700000004								
Yes Item/Each 1 Bottle of 30 Tablets 0037220 NA Box/Carton/Bundle/Inner Pack NA NA					372205222304	00372205222304	COST INFORMATION WHOLESALER USE ONLY:								
Yes Case		48 Bottles in Ca	se			372205222305			JO. IN ORMATION			MOJEOAL	LIC GOL GIVE		
Yes Pallet		416 Bottles in P				372205222309		Regular Cost			Vendor #:				
						Invoice Cost (WAC)	(\$)	\$425.00	Whsl. Code						
								II	11/05/0005		Fineline Co	de:			
								As of date:	11/25/2025						
			Attach copy of SAFETY DA	ATA SHEET (SI	S) or non haza	ard letter, PACKAGE INS	SERT, LABEL AND PHOTO OF	PRODUCT PACKAGING :	and BARCODE.		1				
İ	formation on page	_			- ,oazc		signated Drop Ship Only								



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Version 2024 For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION								
Is this product (check all that apply):								
a. Cytotoxic?	SDS Hazard Classification							
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? No	Organic Corrosive Oxidizer							
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard							
2000 the product abor boar a city top of marning.								
c. Contact Hazard?	Does the product have an Aerosol class? If yes,							
d. Does this product require special clean-up instructions?	identify NFPA Storage Level:							
(If yes, attach SDS with special instructions.)	NFPA Storage Level:							
e. Does the product contain DEHP?								
Is this product regulated for shipment by DOT?	Is the product a NIOSH hazardous drug?							
(if yes, answer a-e below and provide SDS)	If yes, indicate which:							
a. UN/Identification Number b. Proper Shipping Name								
c. DOT Hazard Class	Hazardous Waste Identification							
d. Packing Group								
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics							
Is this product regulated for shipment by IATA?								
(if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS							
a. UN/Identification Number								
b. Proper Shipping Name	Is there a REMS on this product?							
c. DOT Hazard Class d. Packing Group	If Yes, is it managed with a pharmacy registry? Website URL:							
e. Inhalation Hazard?	Website ORL.							
Is the product restricted for air shipment? If so, indicate restriction:	Med Guide Required							
Passenger	Limited Distribution Requirement							
Cargo	Comments / Details: (For example, iPledge program?)							
Passenger & Cargo								
Is this a reportable quantity? No	REMS:							
RQ Threshold:	REMS Program Manager Name: Phone:							
Is this a marine pollutant? No	Supplier Manages REMS registry exclusively:							
Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below)	Wholesale distributor support: Provider Name: DEA #:							
Limited Quantity	Site Enrollment Number assigned 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#	Registry:							
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone:							
	Comments							
Is the Product	RETURN INSTRUCTIONS							
Controlled Substance? Yes Controlled Substance Code 2261 Controlled by State(s)? No Listed Chemical (List I or II) No	RETURN INSTRUCTIONS							
ARCOS Reportable? No If yes, indicate which:	Contact tel. # if product received damaged:							
Schedule No. 3 Is it a scheduled listed chemical product?: No	Is product returnable for credit:							
CLASS OF TRADE RESTRICTION:	URL/Link to returns policy:							
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	7							
Restricted to retail pharmacy only: No	Special regulations or returns requirements for this							
Restricted to hospital, clinics, and physician offices only: No	product in certain states?							
Restricted from US territories? (explain in comments) No	If so, which states? Other requirements? Comments?							
Comments:								
MISCELLAN	IEOUS NOTES and/or Image of Product Barcode:							



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Version 2024

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:	Purchase order daily receipt cut off time by supplier
a. EDI	Cut off time:
b. Autofax Fax Number:	
c. Fax Number:	Shipping lead time of PO: Hours Days
d. Phone only	
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
	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:	Phone: Phone #:
Restricted from US territories? (explain in comments)	Order receipt method: Fax: Fax #:
Comments:	EDI:
	Overnight Fees apply:
	Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	Contact # if product is received damaged:
Physician Name:	Is product returnable for credit:
Physician/Clinic Phone #	URL/Link to returns policy:
Physician State License #	OND LINK to returns policy.
Physician/Clinic DEA #:	Special regulations or returns requirements for this product in certain states?
Physician/Clinic Specialty:	If so, which states? Other requirements? Comments?
Miscellaneous Notes:	
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure?
	Is product order for restocking purposes?