



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

Version 2024

Introduction Type:  New Item Final Version

Date: 12/15/2025

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: Novadoz Pharmaceuticals, LLC	Application Number for NDA/ANDA/BLA; PMA/510(k): 218152	Application: ANDA	NDA 505(b) Type:	a. Temperature – Indicate the USP temperature range for this product.			
Medical Device Class, if applicable:	DUNS: 081109687			Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)			
Proprietary Name (If Applicable) and Established Name: Perampanel Oral Suspension 0.5 mg/mL	Selling Unit NDC: 72205-071-79	Unit of Use NDC:	UPC: 372205071797	Other Temperature Range Requirement (write in)			
UDI:		CVX Code:	MVX Code:	Notes			
Description: 0.5 mg/mL is a white to off-white opaque liquid. It is supplied in a round amber PET bottle with a child-resistant closure. It is packaged with a dispenser set that provides a 20-mL graduated oral dosing syringe and a push-in bottle adapter.				Is this product to be shipped to customers on ice? No			
Active Ingredient(s): Perampanel				Is this product to be shipped to customers on dry ice? No			
URL for Additional Product Information:				b. Contact for temperature excursion questions:			
Address: 20 Duke Road	State: NJ	Address 2: Suite A	Zip: 08854	Name:			
City: Piscataway	Email: sales@novadozpharma.com			Number:			
Key Contact:	Fax:			Group E-mail:			
Phone Number: 908-360-1500				c. Special regulations for product in any states?			
Product Therapeutic Classification:				Special returns requirements for this product?			
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is? a legend device? No if yes, enter class # a product kit? No if yes, list NDCs of component parts reverse numbered? No co-licensed? No latex-free? Yes preservative-free? No correctional institution block? No opioid? No Cannabinoid? No If Unit Dose, is item bar coded to unit dose for hospital scanning? No If Unit Dose, indicate NDC here: 72205-071-79	Is the Product... Direct-Ship Only Is the Product... Neither Orphan Drug Status	FDA Approval Status	Size: 1 (340 mL) Strength: 0.5 mg/mL Dosage Form: Oral Suspension Product Shape: Oral Suspension Product Color: White to off white opaque oral suspension Product Imprint: NA	d. Store product (unit of sale) upright? Protect product (unit of sale) from light?			
Is this product covered under the Trade Agreements Act (TAA)? Yes				e. Shelf life: Initial shelf life at launch (if different):			
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating: AB	Authorized Generic	*If Authorized Generic, other section fields are not applicable					
II. Generic Equivalent to What Brand?: FYCOMPA							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer? Yes	GLN: 0382374000016						
Is product exempt from DSCSA? No	GCP: 0382374						
If yes, select exemption: Other exemption - Write in:							
Is product repackaged? No							
Is product sold by manufacturer's exclusive distributor? No							
Has FDA granted waiver/exception/exemption for product? No	If yes, was original product purchased direct from mfr? Provide source manufacturer for repackaged product						
If yes, attach documentation from FDA.							
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14	ITEM AND PACKING INFORMATION	
Yes Item/Each		1 Carton		00372205071797	00372205071797	Weight Lbs.	Dimensions (US mssmts.)
NA Box/Carton/Bundle/Inner Pack		NA		30372205071798	50372205071792	Depth	Width
Yes Case		8 Cartons in case				Height	Volume (Cube)
Yes Pallet		512 Cartons in pallet				Saleable # Pieces	
COST INFORMATION				WHOLESALER USE ONLY:			
Regular Cost	Vendor #:						
Invoice Cost (WAC) (\$)	Whsl. Code #:						
\$1,500.00	FineLine Code:						
As of date: 12/15/2025				Signature:			

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

See new p. 3 for Designated Drop Ship Only.

\*Please provide any additional information on page 2.



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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?  
Is the product a CA Prop 65 carcinogen?
- c. Is the product a CA Prop 65 reproductive toxicant?
- d. Does the product label bear a CA Prop 65 warning?

No

No

No

No

Yes

Yes

No

No

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

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

c. DOT Hazard Class

d. Packing Group

e. Inhalation Hazard?

Is this product regulated for shipment by IATA?

(If yes, answer a-e below and provide SDS)

a. UN/Identification Number

b. Proper Shipping Name

c. DOT Hazard Class

d. Packing Group

e. Inhalation Hazard?

Is the product restricted for air shipment? If so, indicate restriction:

Yes

Passenger

Cargo

Passager & Cargo

Is this a reportable quantity?

Yes

RQ Threshold:

Is this a marine pollutant?

Yes

Is this product shipped utilizing an authorized DOT exception or Special Permit?

(If yes, identify method below)

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#

## ADD'L STORAGE INFORMATION

Is the Product...

Controlled Substance?

Yes

Controlled Substance Code  2261

Controlled by State(s)?

Yes

Listed Chemical (List I or II)

No

ARCOS Reportable?

No

If yes, indicate which:

Schedule No.

3

Is it a scheduled listed chemical product?:  No

## 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:

## SDS Hazard Classification

Refer SDS

Organic

Inorganic

Steroid/Androgen

Corrosive

Oxidizer

Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:

No

NFPA Storage Level:

Is the product a NIOSH hazardous drug?

No

If yes, indicate which:

## Hazardous Waste Identification

EPA Hazardous Waste Code:  Refer SDS

Waste Characteristics

## REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

No

If Yes, is it managed with a pharmacy registry?

Website URL:

Med Guide Required

Limited Distribution Requirement

Comments / Details: (For example, iPledge program?)

REMS:

REMS Program Manager Name:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:

Site Enrollment Number assigned by Supplier:

Phone:

DEA #:

NCPDP#:

NPI #:

Comments:

Registry:

Registry Program Contact Name:

Phone:

Comments:

## RETURN INSTRUCTIONS

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?

## MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE



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

<b>Order Method for Designated Drop Ship Product</b>		<b>Standard Order Receipt and Processing</b>	
Purchase orders may be accepted by: a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only		Purchase order daily receipt cut off time by supplier Cut off time: <input type="text"/> Hours <input type="text"/> Days	
Fax Number: <input type="text"/> Fax Number: <input type="text"/> Phone No.: <input type="text"/> Site Address: <input type="text"/>		Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days	
Minimum Order Quantity: <input type="text"/>		Ships same day for next day receipt: <input type="text"/> Ships for second day receipt: <input type="text"/> Ships regular ground for 3-10 days receipt: <input type="text"/>	
Supplier's Customer Service Number: <input type="text"/>			
Contracted 3PL company / contact #: Name: <input type="text"/> Phone: <input type="text"/>			
<b>Expedited Freight Charges or Other Designated Drop Ship Fees:</b>		<b>Overnight and Priority Overnight PO Processing</b>	
Expedited freight fees billed with each order: <input type="text"/>		Overnight receipt available: <input type="text"/>	
Drop Ship service fee billed with each order: <input type="text"/>		PO Receipt cut off time: <input type="text"/>	
Drop Ship miscellaneous fees billed: <input type="text"/>		Days of week overnight is available: Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday <input type="checkbox"/>	
Comments: <input type="text"/>			
<b>Class of Trade Restriction:</b>		<b>Priority Overnight receipt available:</b>	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/>		PO Receipt Cut off time: <input type="text"/>	
Restricted to retail pharmacy only: <input type="checkbox"/>		<b>Saturday Overnight receipt available:</b>	
Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/>		PO Receipt Cut off time: <input type="text"/>	
Restricted from US territories? (explain in comments) <input type="text"/>		Order receipt method: Phone: <input type="text"/> Fax: <input type="text"/> EDI: <input type="text"/>	
Comments: <input type="text"/>		Phone #: <input type="text"/> Fax #: <input type="text"/> Overnight Fees apply: Other fees apply: <input type="text"/>	
<b>Other Data Information Required to Process PO:</b>		<b>Return Instructions</b>	
Patient Procedure Date: <input type="text"/>		Contact # if product is received damaged: <input type="text"/>	
Physician Name: <input type="text"/>		Is product returnable for credit: <input type="text"/>	
Physician/Clinic Phone # <input type="text"/>		URL/Link to returns policy: <input type="text"/>	
Physician State License # <input type="text"/>		Special regulations or returns requirements for this product in certain states? <input type="text"/>	
Physician/Clinic DEA #: <input type="text"/>		If so, which states? Other requirements? Comments? <input type="text"/>	
Physician/Clinic Specialty: <input type="text"/>			
<b>Miscellaneous Notes:</b> <input type="text"/>		<b>ADDITIONAL INFORMATION</b>	
		Is product order for scheduled patient procedure? <input type="text"/>	
		Is product order for restocking purposes? <input type="text"/>	