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

Version 2021 | Introduction Type: New Item | Final Version | Date: 11/3/2023

PRODUCT INFORMATION

Company Name: Novadoz Pharmaceuticals LLC | **Application:** ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 215980
Medical Device Class, if applicable:
DUNS: 08-110-9687
Proprietary Name (If Applicable) and Established Name: Levetiracetam Injection, USP 500 mg/5mL (100 mg/mL) (10's Pack)
Selling Unit NDC: 72205-120-07 | **Unit of Use NDC:** | **UPC:** 372205120075
UDI | **CVX Code:** | **MVX Code:**
Description: Levetiracetam injection, USP 500 mg/5 mL injection is a clear, colorless, sterile solution. It is supplied in single-dose 5 mL vials, available in cartons of 10 vials
Active Ingredient(s): Levetiracetam
URL for Additional Product Information:
Address: 20 Duke Road | **Address 2:** Suite A
City: Piscataway | **State:** NJ | **Zip:** 08854
Key Contact: | **Email:** sales@novadozpharma.com
Phone Number: 908-360-1500 | **Fax:** 732-902-2113
Product Therapeutic Classification:

ADDITIONAL PRODUCT INFORMATION

The product is?
- **a legend device?**
- **if yes, enter class #**
- **a product kit?**
- **if yes, list NDCs of component parts**
- **reverse numbered?**
- **co-licensed?** No
- **latex-free?** Yes
- **preservative-free?** Yes
- **correctional institution block?**
- **opioid?** No
- **Cannabinoid?** No

If Unit Dose, is item bar coded to unit dose for hospital scanning?
If Unit Dose, indicate NDC here: 72205-120-07

Is the Product… Direct-Ship Only
Is the Product… Neither
Orphan Drug Status
FDA Approval Status
Allergens Present
Country of Origin
Is this product covered under the Trade Agreements Act (TAA)? No

PRODUCT DESCRIPTION INFORMATION

Size: 10 vials
Strength: 500 mg/5mL (100 mg/mL)
Dosage Form: Injection
Product Shape: N/A
Product Color: Clear/colorless
Product Imprint: N/A

FOR GENERIC DRUG PRODUCTS

Authorized Generic | *If Authorized Generic, other section fields are not applicable
I. Orange Book Rating:
II. Generic Equivalent to What Brand?:

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes
Is product exempt from DSCSA? No
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, attach documentation from FDA.

GLN: 8904159670843
GCP: 89041596
If yes, was original product purchased direct from mfr?
Provide source manufacturer for repackaged product

GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure		Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
Yes	Item/Each	1 Carton Pack		00372205120075	00372205120075
Yes	Box/Carton/Bundle/Inner Pack	3 Cartons in Outer pack		20372205120079	
Yes	Case	6 Outer Cartons in case		30372205120076	
Yes	Pallet	1,440 Cartons in pallet		50372205120070	

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.
Temperature Range: Controlled Room – between 20 and 25 C (68° – 77° F)
Other Temperature Range Requirement (write in): NA
Notes
Is this product to be shipped to customers on ice? No
Is this product to be shipped to customers on dry ice? No

b. Contact for temperature excursion questions:
Name: T Ch Hanumantha Rao
Number: 040-3044 9212/9362
Group E-mail: chrao.t@msnlabs.com

c. Special regulations for product in any states? No
Special returns requirements for this product? No

d. Store product (unit of sale) upright? Yes
Protect product (unit of sale) from light? Yes
e. Shelf life: 24 Months
Initial shelf life at launch (if different): 24 Months

ORDER INFORMATION

Unit of Sale
- Bottle
- x Box/Carton
- Ampule
- Glass
- Tube
- Vial Liquid Sgl
- Vial Liquid Multi
- Vial Powder Sql
- Vial Power Multi
- Other: Write In

What is the NDC selling unit? 1 carton of 10 vials (Write-in, e.g. 1 Box of 10 Vials)
Minimum order quantity?
If Yes, how many of which package type?
- Each
- Inner/Carton/Pack
- Case

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer? 1 carton of 10 vials (Write-in, e.g. 1 Vial)
Rx billing unit to pharmacy:
- x Each
- Gram
- Milliliter

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Width	Height	Volume (Cube)	Saleable # Pieces
Item/Each:	0.437	4.803	1.968	2.165	20.464	1
Box/Carton/Bundle/ Inner Pack:	1.472	6.6	5.43	2.67	96.2	3
Case:	9.92	12.204	7.874	9.645	926.82	18
Pallet:	833.347	47.24	39.37	44.48	82,740.50	1440

COST INFORMATION

Regular Cost
Invoice Cost (WAC) ($) $29.95
As of date: 11/3/2023

WHOLESALER USE ONLY:

Vendor #:
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.

***Please provide any additional information on page 2.**
See new p. 3 for Designated Drop Ship Only.
Signature:

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

Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic?	No
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	
Is the product a CA Prop 65 carcinogen?	No
Is the product a CA Prop 65 reproductive toxicant?	No
Does the product label bear a CA Prop 65 warning?	No
c. Contact Hazard?	No
d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)	No
e. Does the product contain DEHP?	No
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS)	No
a. UN/Identification Number	
b. Proper Shipping Name	
c. DOT Hazard Class	
d. Packing Group	
e. Inhalation Hazard?	No
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)	No
a. UN/Identification Number	
b. Proper Shipping Name	
c. DOT Hazard Class	
d. Packing Group	
e. Inhalation Hazard?	No
Is the product restricted for air shipment? If so, indicate restriction:	No

- [ ] Passenger
- [ ] Cargo
- [ ] Passenger & Cargo

Is this a reportable quantity?	No
RQ Threshold:	
Is this a marine pollutant?	No

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

No (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#

SDS Hazard Classification

- [ ] 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:		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	No
Limited Distribution Requirement	No
Comments / Details: (For example, iPledge program?)	

REMS: No

REMS Program Manager Name:		Phone:	
Supplier Manages REMS registry exclusively:			
Wholesale distributor support:			
Provider Name:		DEA #:	
Site Enrollment Number assigned by Supplier:		NCPDP#:	
		NPI #:	
Comments			

Registry: No

Registry Program Contact Name:		Phone:	
Comments			

ADD'L STORAGE INFORMATION

Is the Product…

Controlled Substance?	No	Controlled Substance Code	
Controlled by State(s)?	No	Listed Chemical (List I or II)	No
ARCOS Reportable?	No	If yes, indicate which:	
Schedule No.		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	Yes
Restricted to retail pharmacy only:	No
Restricted to hospital, clinics, and physician offices only:	No
Restricted from US territories? (explain in comments)	No
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?	No
If so, which states? Other requirements? Comments?	

MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE

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Version 2021

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

Order Method for Designated Drop Ship Product

Purchase orders may be accepted by:

a. EDI
b. Autofax — Fax Number:
c. Fax — Fax Number:
d. Phone only — Phone No.:
e. Supplier Web Site only — Site Address:

Minimum Order Quantity:

Supplier's Customer Service Number:

Contracted 3PL company / contact #: Name:
Phone:

Standard Order Receipt and Processing

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:

Expedited Freight Charges or Other Designated Drop Ship Fees:

Expedited freight fees billed with each order:

Drop Ship service fee billed with each order:

Drop Ship miscellaneous fees billed:

Comments:

Overnight and Priority Overnight PO Processing

Overnight receipt available:

PO Receipt cut off time:

Days of week overnight is available:
- Monday
- Tuesday
- Wednesday
- Thursday
- Friday

Priority Overnight receipt available:

PO Receipt Cut off time:

Saturday Overnight receipt available:

PO Receipt Cut off time:

Order receipt method:
Phone: Phone #:
Fax: Fax #:
EDI:

Overnight Fees apply:
Other fees apply:

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:

Other Data Information Required to Process PO:

Patient Procedure Date:
Physician Name:
Physician/Clinic Phone #
Physician State License #
Physician/Clinic DEA #:
Physician/Clinic Specialty:

Return Instructions

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?