



Date: 3/11/2021

PRODUCT INFORMATION						SPECIAL HANDLING AND STORAGE REQUIREMENTS*							
Company Name: Novadoz Pharmaceuticals, LLC						Application:		ANDA					
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):						209357							
DUNS:						08-110-9687							
Proprietary Name (If Applicable) and Established Name:						Pregabalin Capsules 225mg							
Selling Unit NDC:		72205-017-90		Unit of Use NDC:				UPC:		372205017900			
UDI				CVX Code:				MXV Code:					
Description:						White to off white color granular powder filled in size "1" hard gelatin capsules with white Opaque body imprinted "PGBN" and light blue Opaque cap imprinted "225" with black ink.							
Active Ingredient(s):						Pregabalin							
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:													
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)													
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:				P. Krishna Reddy									
Number:				040-30449311									
Group E-mail:				krishna_p@msnlabs.com									
c. Special regulations for product in any states?													
				Special returns requirements for this product?				No					
d. Store product (unit of sale) upright?													
				Protect product (unit of sale) from light?				Yes					
e. Shelf life:				Initial shelf life at launch (if different):				36 Months		Months			
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? co-licensed? No latex-free? Yes preservative-free? Yes correctional institution block? opioid? No cannabinoid? No						Is the Product... Direct-SHIP Only Is the Product... Neither Orphan Drug Status FDA Approval Status Allergens Present No Country of Origin India						Size: 90 Strength: 225mg Dosage Form: Capsule Product Shape: Capsule Product Color: White body, blue cap Product Imprint: Body - PGBN, Cap - 225	
If Unit Dose, is item bar coded to unit dose for hospital scanning? If Unit Dose, indicate NDC here:						Is this product covered under the Trade Agreements Act (TAA)? No							
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?: Lyrica													
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION													
Does supplier meet DSCSA definition of manufacturer?						Yes		GLN:					
Is product exempt from DSCSA?						No							
If yes, select exemption:													
Other exemption - Write in:													
Is product repackaged?						No		If Yes, was original product purchased direct from mfr?					
Is product sold by manufacturer's exclusive distributor?						No		If yes, attach documentation from FDA.					
Has FDA granted waiver/exception/exemption for product?						No							
GTIN AND HIBCC PRODUCT INFORMATION													
Saleable Unit of Measure		Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14								
Item/Each		1		00372205017900									
Box/Carton/Bundle/Inner Pack													
X Case		48		30372205017901									
Pallet		2304		50372205017905									
PHARMACY ORDER / BILL UNIT													
Rec. sell unit to customer?						1 Bottle		Rx billing unit to pharmacy:					
(Write-in, e.g. 1 Vial)								48 Each					
								Gram					
								1 Milliliter					
ITEM AND PACKING INFORMATION													
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:							
		Depth	Width	Height									
Box/Carton/Bundle/ Inner Pack:	NA	NA	NA	NA	NA	NA							
Case:	8.33	12.4	8.46	10.62	1114.0805	48							
Pallet:	439.85	47.24	39.37	37.79	70283.308	2304							
COST INFORMATION						WHOLESALE USE ONLY:							
Regular Cost						Vendor #:							
Invoice Cost (WAC) (\$)				\$7.50		Whsl. Code #:							
As of date:				5/7/2020		Fineline Code:							
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING AND BARCODE.													



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

Version 2020

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? ☐ No
- (If yes, attach SDS with special instructions.)
- 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:

- ☐ 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#

ADD'L STORAGE INFORMATION

Is the Product...

- Controlled Substance? ☐ Yes Controlled Substance Code
- Controlled by State(s)? ☐ Yes 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:

SDS Hazard Classification

- ☐ Organic ☐ Corrosive
- ☐ Inorganic ☐ Oxidizer
- ☐ Steroid/Androgen ☐ Contact Hazard

☐ Aerosol Class; Identify 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: PCPDP#:

NPI #:

Comments

Registry: ☐ No

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? ☐ No

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.

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone: Fax Number: Fax Number: Phone No.: Site Address:	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:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	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:	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?