



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

Version 2020

Introduction Type: ☒ Final VersionDate:

PRODUCT INFORMATION			
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 25mg			
Selling Unit NDC: 72205-011-90		Unit of Use NDC:	UPC: 372205011908
UDI:		CVX Code:	MXV Code:
Description: White to off white color granular powder filled in size '4' hard gelatin capsules with white Opaque body imprinted 'PGBN' and light blue Opaque cap imprinted '25' 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:			

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is?		Is the Product... Direct-Ship Only	
a legend device?	No	Is the Product... Neither	
if yes, enter class #		Orphan Drug Status	
a product kit?	No	FDA Approval Status	
if yes, list NDCs of component parts		Allergens Present	No
reverse numbered?	No	Country of Origin	India
co-licensed?	No	Is this product covered under the Trade Agreements Act (TAA)?	No
latex-free?	Yes		
preservative-free?	Yes		
correctional institution block?	No		
opioid?	No		
Cannabinoid?	No		
If Unit Dose, is item bar coded to unit dose for hospital scanning?			
If Unit Dose, indicate NDC here:			
Size:	90	Strength:	25mg
Dosage Form:	Capsule	Product Shape:	Capsule
Product Color:	White body, blue cap	Product Imprint:	Body - PGBN, Cap - 25

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		00372205011908	
☐ Box/Carton/Bundle/Inner Pack			30372205011909	
☒ Case	48		50372205011903	
☐ Pallet	4416			

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)					
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@msnlab.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	

ORDER INFORMATION			
Unit of Sale	What is the NDC selling unit?		
☒ Bottle	1 Bottle of 90 Tablets		
☐ Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)		
☐ Ampule			
☐ Glass	Minimum order quantity? Yes		
☐ Tube			
☐ Vial Liquid Sgl			
☐ Vial Liquid Multi			
☐ Vial Powder Sgl	If Yes, how many of which package type?		
☐ Vial Powder Multi	48	Each	
☐ Other: Write in	1	Inner/Carton/Pack	
		Case	

PHARMACY ORDER / BILL UNIT			
Rec. sell unit to customer?	Rx billing unit to pharmacy:		
1 Bottle	☒ Each		
(Write-in, e.g. 1 Vial)	Gram		
	Milliliter		

ITEM AND PACKING INFORMATION						
	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Width	Height		
Item/Each:	0.085	1.609	1.609	3.89	10.070747	1
Box/Carton/Bundle/Inner Pack:	NA	NA	NA	NA	NA	NA
Case:	5.01	10.43	7.29	9.45	718.52792	48
Pallet:	500.5	47.24	39.37	43.7	81274.956	4416

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$6.00	Whsl. Code #:	
As of date:	5/7/2020	Fineline Code:	

*Please provide any additional information on page 2.

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.

Signature:



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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?	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?	No		
(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?	No		
Is this product regulated for shipment by IATA?	No		
(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?	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	2782
Controlled by State(s)?	Yes	Listed Chemical (List I or II)	No
ARCOS Reportable?	No	If yes, indicate which:	
Schedule No.	5	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 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:	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?