



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

Version 2020

Introduction Type: ☒ Final VersionDate:

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 50mg Selling Unit NDC: 72205-012-90 Unit of Use NDC: UPC: 372205012905 UDI: CVX Code: MXV Code: Description: <input "50"="" "pgbn"="" 4"="" and="" black="" blue="" body="" cap="" capsules="" gelatin="" hard="" imprinted="" ink."="" light="" opaque="" type="text" value="White to off white color granular powder filled in size " white="" with=""/> Active Ingredient(s): Pregabalin URL for Additional Product Information: Address: 20 Duke Road City: Piscataway State: NJ Address 2: Suite A Zip: 08854 Key Contact: Phone Number: 908-360-1500 Email: sales@novadozpharma.com Product Therapeutic Classification: Fax: 732-902-2113				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			
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? 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:		Is the Product... Is the Product... Orphan Drug Status FDA Approval Status Allergens Present No Country of Origin India Is this product covered under the Trade Agreements Act (TAA)? No		Direct Ship Only Neither Size: 90 Strength: 50mg Dosage Form: Capsule Product Shape: Capsule Product Color: White body, blue cap Product Imprint: Body - PGBN, Cap - 50			
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 ☐ Item/Each ☒ Box/Carton/Bundle/Inner Pack ☒ Case ☐ Pallet		Quantity 1 48 4416	HIBCC	GTIN-14 00372205012905 30372205012906 50372205012900	Unit of Use GTIN-14		
ITEM AND PACKING INFORMATION							
	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:	
		Depth	Width	Height			
Item/Each:	0.093	1.609	1.609	3.89	10.070747	1	
Box/Carton/Bundle/Inner Pack:	NA	NA	NA	NA	NA	NA	
Case:	5.35	10.43	7.29	9.45	718.52792	48	
Pallet:	532.65	47.24	39.37	43.7	81274.956	4416	
COST INFORMATION							
Regular Cost		Vendor #:					
Invoice Cost (WAC) (\$)		\$6.00		Whsl. Code #:			
As of date: 5/7/2020				Fineline Code:			
WHOLESALE USE ONLY:							
Signature:							

*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?

(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? ☐