

Version 2021

Introduction Type: Post Launch Change

Final Version

Date: 2/11/2024

PRODUCT INFORMATION			
Company Name: Novadoz Pharmaceuticals LLC		Application: ANDA	
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 218306			
Medical Device Class, if applicable:			
DUNS: 081109687			
Proprietary Name (if Applicable) and Established Name: Lisdexametamine dimesylate chewable tablets 10mg/100's			
Selling Unit NDC: 72205-132-91		Unit of Use NDC:	UPC: 372205132917
UDI:		CVX Code:	MXV Code:
Description: Lisdexametamine dimesylate chewable tablets 10 mg: White or off-white to mottled round shaped tablet debossed with 'm169' on one side and plain on the other side			
Active Ingredient(s): Lisdexametamine dimesylate			
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? a legend device?	No	Is the Product... Is the Product... Orphan Drug Status	Direct-Ship Only Neither
if yes, enter class # a product kit?	No	FDA Approval Status	
if yes, list NDCs of component parts reverse numbered? co-licensed?	No	Allergens Present	No
latex-free?	Yes	Country of Origin	USA
preservative-free?	Yes		
correctional institution block?	No		
opioid?	No		
Cannabinoid?	No		
If Unit Dose, is item bar coded to unit dose for hospital scanning?		Is this product covered under the Trade Agreements Act (TAA)?	
If Unit Dose, indicate NDC here: 72205-132-91		No	
FOR GENERIC DRUG PRODUCTS			
I. Orange Book Rating: AB		Authorized Generic	
II. Generic Equivalent to What Brand?: Vyvanse		*If Authorized Generic, other section fields are not applicable	
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:		GLN: 0382374000016	
Is product repackaged?		GCP: 0382374	
Is product sold by manufacturer's exclusive distributor?		If yes, was original product purchased direct from mfr?	
Has FDA granted waiver/exception/exemption for product?		Provide source manufacturer for repackaged product	
If yes, attach documentation from FDA.			
GTIN and HIBCC PRODUCT INFORMATION			
Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14
Yes NA Yes Yes	Item/Each Box/Case/Bundle/Inner Pack Case Pallet	1 Bottle of 100 tablets NA 48 Bottles in case 1872 Bottles in pallet	Unit of Use GTIN-14 00372205132917 30372205132918 50372205132912
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:			

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:					
Number:					
Group E-mail:					
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):		24 Months			
ORDER INFORMATION					
Unit of Sale		What is the NDC selling unit?			
x Bottle		1 bottle of 100 tablets			
Box/Case/Bundle/Inner Pack		(Write-in, e.g. 1 Box of 10 Vials)			
Ampule		Minimum order quantity?			
Glass		Yes			
Tube					
Vial Liquid Sgl		If Yes, how many of which package type?			
Vial Liquid Multi		48 Each			
Vial Powder Sgl		Inner/Case/Pack			
Vial Powder Multi		Case			
Other: Write In					
PHARMACY ORDER / BILL UNIT					
Rec. sell unit to customer?		Rx billing unit to pharmacy:			
1 bottle		x Each			
(Write-in, e.g. 1 Vial)		Gram			
		Milliliter			
ITEM AND PACKING INFORMATION					
	Weight Lbs.	Dimensions (US msmts.)		Volume (Cube)	Saleable #
		Depth	Width	Height	Pieces
Item/Each:	0.162	NA	2.045	4.355	141
Box/Case/Bundle/Inner Pack:	NA	NA	NA	NA	NA
Case:	8.83	13.19	9.055	10.039	1,199.01
Pallet:	383.92	47.24	39.37	36.023	66,996.97
					1872
COST INFORMATION			WHOLESALE USE ONLY:		
Regular Cost			Vendor #:		
Invoice Cost (WAC) (\$)		\$1,107.95	Whsl. Code #:		
As of date:		7/30/2024	Fineline Code:		