

Version 2021

Introduction Type:

x Final Version

Date: 5/1/2022

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: Novadoz Pharmaceuticals, LLC Application: ANDA				a. Temperature – Indicate the USP temperature range for this product.			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):				Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)			
Medical Device Class, if applicable:				Other Temperature Range Requirement			
DUNS: 08-110-9687				(write in)			
Proprietary Name (If Applicable) and Established Name:				Notes			
Selling Unit NDC: 72205-019-01 Unit of Use NDC: UPC: 372205019010				Is this product to be shipped to customers on ice? No			
UDI CVX Code: MX Code:				Is this product to be shipped to customers on dry ice? No			
Description: Valganciclovir for Oral Solution 50 mg/mL (100 mL)				b. Contact for temperature excursion questions:			
Active Ingredient(s): Valganciclovir				Name: P. Krishna Reddy			
URL for Additional Product Information:				Number: 040-30449311			
Address: 20 Duke Road				Group E-mail: krishna_p@msnlabs.com			
City: Piscataway				c. Special regulations for product in any states?			
Key Contact: Seshu Akula				Special returns requirements for this product? No			
Phone Number: 908-887-0679				d. Store product (unit of sale) upright? Yes			
Product Therapeutic Classification:				Protect product (unit of sale) from light? Yes			
				e. Shelf life: Months			
				Initial shelf life at launch (if different): Months			
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is?				Size: 100ml			
a legend device? No				Strength: 50mg/ml			
if yes, enter class #				Dosage Form: Powder for oral suspension			
a product kit? No				Product Shape: NA			
if yes, list NDCs of component parts				Product Color: White			
reverse numbered? No				Product Imprint: NA			
co-licensed? No							
latex-free?							
preservative-free?							
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: 72205-019-01							
Is the Product...							
Is the Product...							
Orphan Drug Status							
FDA Approval Status							
Allergens Present							
Country of Origin US							
Is this product covered under the Trade Agreements Act (TAA)? Yes							
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?: Valcyte							
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.							
GTIN and HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure							
Saleable Quantity							
HIBCC							
GTIN-14							
Unit of Use GTIN-14							
Yes Item/Each							
NA Box/Carton/Bundle/Inner Pack							
Yes Case							
Yes Pallet							
Weight Lbs.							
Dimensions (US msmts.)							
Volume (Cube)							
Saleable # Pieces							
Item/Each:							
Box/Carton/Bundle/Inner Pack:							
Case:							
Pallet:							
COST INFORMATION							
WHOLESALE USE ONLY:							
Regular Cost							
Invoice Cost (WAC) (\$)							
As of date:							
Vendor #:							
Whsl. Code #:							
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: