



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

Version 2021

Introduction Type: ☐ New Item☒ Final Version

Date: 11/5/2024

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): 216948 Medical Device Class, if applicable: DUNS: 081109687 Proprietary Name (If Applicable) and Established Name: Nelarabine Injection 250 mg/50 mL (5 mg/mL) Mono carton (1 x 50 mL) Selling Unit NDC: 72205-154-01 Unit of Use NDC: UPC: 372205154018 UDI CVX Code: MVX Code: Description: Nelarabine Injection 250 mg/50 mL (5 mg/mL) Mono carton (1 x 50 mL) Active Ingredient(s): Nelarabine 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: Indicated for the treatment of adults and children who have T-cell acute lymphoblastic leukemia and T-cell Lymphoblastic lymphoma.				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: T Ch Hanumantha Rao Number: 040-3044 9212/9362 Group E-mail: chrao.t@msnlabs.com c. Special regulations for product in any states? Special returns requirements for this product? No d. Store product (unit of sale) upright? Yes e. Shelf life: Protect product (unit of sale) from light? Initial shelf life at launch (if different): 24 Months					
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION					
The product is? a legend device? if yes, enter class # a product kit? 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 If Unit Dose, is item bar coded to unit dose for hospital scanning? If Unit Dose, indicate NDC here: 72205-154-01		Is the Product... Is the Product... Direct-Ship Only Orphan Drug Status Neither FDA Approval Status Allergens Present Country of Origin Is this product covered under the Trade Agreements Act (TAA)? No		Size: 50ml Strength: 250mg/50mL(5mg/mL) Dosage Form: Liquid Injection Product Shape: Product Color: Clear Colorless solution Product Imprint: NA					
FOR GENERIC DRUG PRODUCTS									
I. Orange Book Rating: AP Authorized Generic ☐ *If Authorized Generic, other section fields are not applicable II. Generic Equivalent to What Brand?: Arranon									
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.				GLN: 8904159670843 GCP: 89041596 If yes, was original product purchased direct from mfr? Provide source manufacturer for repackaged product					
GTIN AND HIBCC PRODUCT INFORMATION									
Saleable Unit of Measure Yes Item/Each Yes Box/ Carton/ Bundle/ Inner Pack Yes Case Yes Pallet		Saleable Quantity 1 Carton Pack 08 Mono Cartons in Outer pack 06 Outer packs in case 1920 Mono cartons in Pallet		HIBCC 		GTIN-14 00372205154018 20372205154012 30372205154019 50372205154013 		Unit of Use GTIN-14 00372205154018	
ORDER INFORMATION				PHARMACY ORDER / BILL UNIT					
Unit of Sale ☒ Bottle ☒ Box/ Carton ☐ Ampule ☐ Glass ☐ Tube ☐ Vial Liquid Sgl ☐ Vial Liquid Multi ☐ Vial Powder Sgl ☐ Vial Powder Multi ☐ Other: Write In				What is the NDC selling unit? 1 box of 1 vial (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity? Yes If Yes, how many of which package type? 1 Each Inner/ Carton/ Pack Case					
Rec. sell unit to customer? 1 Vial (Write-in, e.g. 1 Vial)				Rx billing unit to pharmacy: Each Gram Milliliter					
ITEM AND PACKING INFORMATION									
		Weight Lbs.		Dimensions (US msmts.)		Volume (Cube)		Saleable # Pieces	
		Depth		Width		Height			
Item/Each:		0.284		1.96		1.77		3.34	
Box/ Carton/ Bundle/ Inner Pack:		2.612		7.48		4.21		3.74	
Case:		16.625		9.64		8.85		12.99	
Pallet:		704.685		47.24		39.37		31.88	
								59,292	
								1920	
COST INFORMATION				WHOLESALE USE ONLY:					
Regular Cost Invoice Cost (WAC) (\$) \$661.00 As of date: 10/21/2024				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:									



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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? (If yes, attach SDS with special instructions.)	☐ No		
e. Does the product contain DEHP?	☐ No		
Is this product regulated for shipment by DOT? (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? (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:		☐ No	
☐ 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?	☐ No	Controlled Substance Code	
Controlled by State(s)?	☐ No	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:			
MISCELLANEOUS NOTES and/or Image of Product Barcode:			

SDS Hazard Classification	
☐ Organic	☐ Corrosive
☐ Inorganic	☐ Oxidizer
☐ Steroid/Androgen	☐ Contact Hazard
Does the product have an Aerosol class? If yes, identify NFPA Storage Level:	
NFPA Storage Level:	☐ No
Is the product a NIOSH hazardous drug?	
If yes, indicate which:	☐ Yes
Group 2 items (non-antineoplastic that meets a hazard criterion)	

Hazardous Waste Identification	
EPA Hazardous Waste Code:	Waste Characteristics

REMS or REGISTRY RESTRICTIONS	
Is there a REMS on this product?	
If Yes, is it managed with a pharmacy registry?	☐ No
Website URL:	
Med Guide Required	
Limited Distribution Requirement	☐ No
Comments / Details: (For example, iPledge program?)	
REMS:	
REMS Program Manager Name:	☐ No
Supplier Manages REMS registry exclusively:	
Wholesale distributor support:	
Provider Name:	
Site Enrollment Number assigned by Supplier:	
DEA #:	
NCPDP#:	
NPI #:	
Comments	
Registry:	
Registry Program Contact Name:	☐ No
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?	
If so, which states? Other requirements? Comments:	☐ No



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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: Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight and Priority Overnight PO Processing 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: Patient Procedure Date: Physician Name: Physician/Clinic Phone #: Physician State License #: Physician/Clinic DEA #: Physician/Clinic Specialty:	Return Instructions 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? ☐