

Version 2024

Introduction Type:

x Final Version

Date: 8/27/2026

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: Novadoz Pharmaceuticals, LLC Application Number for NDA/ANDA/BLA; PMA/510(k): 209775 Application: ANDA Medical Device Class, if applicable: NDA 505(b) Type: DUNS: 08-110-9687 Proprietary Name (If Applicable) and Established Name: Clofarabine Injection 20 mg/20 mL (1 mg/mL) Selling Unit NDC: 72205-394-01 UDI: CVX Code: UPC: 372205394018 MX Code: Description: Clear colorless solution free from visible particle matter in 20mL tubular USP Type-I clear vial with 20mm bromobutyl rubber stopper and sealed with Aluminium seal having polypropylene disc Active Ingredient(s): Clofarabine URL for Additional Product Information: Address: 20 Duke Road City: Piscataway Key Contact: Phone Number: 908-360-1500 Product Therapeutic Classification: Address 2: Suite A State: NJ Email: Sales@novadozpharma.com Zip: 08854 Fax: 678-608-3778							

ADDITIONAL PRODUCT 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? latex-free? preservative-free? correctional institution block? opioid? Cannabinoid? 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 Country of Origin Is this product covered under the Trade Agreements Act (TAA)? Direct-Ship Only Neither India No				PRODUCT DESCRIPTION INFORMATION Size: Strength: Dosage Form: Product Shape: Product Color: Product Imprint: 20 ml Vial 20 mg Injection vials Clear colorless																																																																		
FOR GENERIC DRUG PRODUCTS I. Orange Book Rating: AB II. Generic Equivalent to What Brand?: CLOLAR Authorized Generic *If Authorized Generic, other section fields are not applicable				ORDER INFORMATION Unit of Sale What is the NDC selling unit? Minimum order quantity? If Yes, how many of which package type? x Bottle Box/ Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sgl Vial Powder Multi Other: Write In 1 Box of 1 Vial (Write-in, e.g. 1 Box of 10 Vials) x Each Inner/ Carton/ Pack Case																																																																		
I. Orange Book Rating: AB II. Generic Equivalent to What Brand?: CLOLAR Authorized Generic *If Authorized Generic, other section fields are not applicable				PHARMACY ORDER / BILL UNIT Rec. sell unit to customer? Rx billing unit to pharmacy: HCP's J-Code: (Write-in, e.g. 1 Vial) x Each Gram Milliliter																																																																		
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION Does supplier meet DSCSA definition of manufacturer? Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's exclusive distributor? Has FDA granted waiver/exception/exemption for product? If yes, attach documentation from FDA. Yes No No No No GLN: GCP: If yes, was original product purchased direct from mfr? Provide source manufacturer for repackaged product 8904159670843 89041596				ITEM AND PACKING INFORMATION	Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces		----------------------------------	-------------	------------------------	-------	--------	---------------	-------------------				Depth	Width	Height				Box/ Carton/ Bundle/ Inner Pack:	1.01	5.7	3.74	2.95	62.89	8		Pallet:	768.09	47.24	39.37	44.29	82372.26	5,120																											
GTIN AND HIBCC PRODUCT INFORMATION	Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14		--------------------------	---------------------------------	--------------------------	-------	----------------	---------------------		Yes	Item/Each	1 vial in carton		00372205394018	00372205394018		NA	Box/ Carton/ Bundle/ Inner Pack	8 Catons in outer carton		20372205394012			Yes	Case	64 cartons in case		30372205394019			Yes	Pallet	5120 Cartons in pallet		50372205394013																											COST INFORMATION Regular Cost Invoice Cost (WAC) (\$) As of date: \$250.00 8/27/2026 Vendor #: Whsl. Code #: Fineline Code:			
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.				Signature:																																																																		



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

Version 2024

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

- a. Cytotoxic? ☐ Yes
- 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? ☐ Yes
Does the product label bear a CA Prop 65 warning? ☐ No

- c. Contact Hazard? ☐ Yes
- d. Does this product require special clean-up instructions?
(If yes, attach SDS with special instructions.) ☐ Yes
- 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 2811
- b. Proper Shipping Name Toxic solid , organic , n.o.s (Clofarabine)
- c. DOT Hazard Class 6.1 (Toxic)
- d. Packing Group I
- 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 2811
- b. Proper Shipping Name Toxic solid , organic , n.o.s (Clofarabine)
- c. DOT Hazard Class 6.1 (Toxic)
- d. Packing Group I
- 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? ☐

Is this product shipped utilizing an authorized DOT exception or Special Permit?

☐ (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?: ☐

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:

SDS Hazard Classification

Refer SDS

- ☒ Organic ☐ Corrosive
- ☐ Inorganic ☐ Oxidizer
- ☐ Steroid/Androgen ☐ Contact Hazard

Does the product have an Aerosol class? If yes,
identify NFPA Storage Level:

No

NFPA Storage Level:

Is the product a NIOSH hazardous drug?

No

If yes, indicate which:

Group 1 items (antineoplastic)

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

NCPDP#:

by Supplier:

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?

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: 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?