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

Version 2021 | Introduction Type: New Item | Final Version | Date: 06.04.2024

PRODUCT INFORMATION

Company Name: Novadoz Pharmaceuticals LLC | Application: ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 214814
Medical Device Class, if applicable:
DUNS: 081109687
Proprietary Name (If Applicable) and Established Name: Carmustine for Injection, USP 100 mg/vial
Selling Unit NDC: 72205-198-01 | Unit of Use NDC: | UPC: 372205198012
UDI: | CVX Code: | MVX Code:
Description: **Before Reconstitution:** Pale yellow flakes or congealed mass in a 20 mm neck 30ml USP Type- I amber moulded glass vial with 20 mm rubber stopper and sealed with 20 mm aluminium seal having yellow colour propylene disc. & Diluent -Clear colorless, mobile, volatile liquid free from visible particles in 5 mL type-I clear tubular glass vial with 20 mm rubber stopper and sealed with 20 mm aluminium seal having polypropylene disc **After Reconstitution;** Clear Color less to yellowish solution free from visible particles.
Active Ingredient(s): Carmustine USP
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: Anti Cancer

ADDITIONAL PRODUCT INFORMATION

The product is?		Is the Product…	Direct-Ship Only
a legend device?		Is the Product…	Neither
if yes, enter class #		Orphan Drug Status	
a product kit?	Yes		
if yes, list NDCs of component parts	72205-197-01 & 72205-196-01	FDA Approval Status	
reverse numbered?			
co-licensed?	No	Allergens Present	
latex-free?	Yes		
preservative-free?	Yes		
correctional institution block?			
opioid?	No		
Cannabinoid?	No	Country of Origin	
If Unit Dose, is item bar coded to unit dose for hospital scanning?			
If Unit Dose, indicate NDC here:	72205-198-01	Is this product covered under the Trade Agreements Act (TAA)?	No

PRODUCT DESCRIPTION INFORMATION

Size: 1
Strength: 100mg
Dosage Form: Injectable
Product Shape:
Product Color: yellowish solution
Product Imprint: N/A

FOR GENERIC DRUG PRODUCTS

Authorized Generic | *If Authorized Generic, other section fields are not applicable
I. Orange Book Rating: AP
II. Generic Equivalent to What Brand?: BiCNU

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		Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
Yes	Item/Each	1		00372205198012	00372205198012
Yes	Box/Carton/Bundle/Inner Pack	4 mono cartons per outer carton		20372205198016	
Yes	Case	64 mono cartons per shipper		30372205198013	
Yes	Pallet	1536 mono cartons per shipper		50372205198017	

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.
Temperature Range: Cold – between 2 and 8 C (36° – 46° 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? No
Special returns requirements for this product? No

d. Store product (unit of sale) upright? Yes
Protect product (unit of sale) from light? Yes

e. Shelf life: 24 Months
Initial shelf life at launch (if different): Months

ORDER INFORMATION

Unit of Sale

	Bottle
x	Box/Carton
	Ampule
	Glass
	Tube
	Vial Liquid Sgl
	Vial Liquid Multi
	Vial Powder Sql
	Vial Power Multi
	Other: Write In

What is the NDC selling unit?
72205-198-01
(Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity? Yes

If Yes, how many of which package type?

4	Each
	Inner/Carton/Pack
	Case

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer:
1 carton that includes a vial containing 100mg carmustine and a vial containing 3ml sterile diluent
(Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy:

x	Each
	Gram
	Milliliter

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Width	Height	Volume (Cube)	Saleable # Pieces
Item/Each:	0.227	3.38	1.84	3.35	20.83	1
Box/Carton/Bundle/ Inner Pack:	1.128	7.08	3.94	3.54	98.75	4
Case:	20.117	17.32	15.75	8.85	2,414.19	64
Pallet:	522.49	47.24	39.37	41.33	76,867	1,536

COST INFORMATION

Regular Cost:
Invoice Cost (WAC) ($): $450.00
As of date: 4/25/2024

WHOLESALER USE ONLY:

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.

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)	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:	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#

SDS Hazard Classification

- ☐ Organic
- ☐ Inorganic
- ☐ Steroid/Androgen
- ☐ Corrosive
- ☐ Oxidizer
- ☐ 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:	

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:		NCPDP#:	
		NPI #:	
Comments			
Registry:	No		
Registry Program Contact Name:		Phone:	
Comments			

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:	

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

Purchase orders may be accepted by:

a. EDI
b. Autofax — Fax Number:
c. Fax — Fax Number:
d. Phone only — Phone No.:
e. Supplier Web Site only — Site Address:

Minimum Order Quantity:
Supplier's Customer Service Number:
Contracted 3PL company / contact #: Name:
Phone:

Standard Order Receipt and Processing

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?