



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

Version 2024

Introduction Type: ☐ Post Launch Change☐ Final VersionDate:

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*																																																													
Company Name: EUGIA US LLC Application Number for NDA/ANDA/BLA; PMA/510(k): 205487 Medical Device Class, if applicable: DUNS: 968961354 Proprietary Name (If Applicable) and Established Name: CARBOplatin Injection, 450 mg/45 mL MDV Selling Unit NDC: 55150-335-01 Unit of Use NDC: 55150-335-01 UPC: 355150335015 CVX Code: MVX Code: Description: CARBOplatin Injection 450mg/45 mL (10mg/mL) [MDV] [Mono Pack] Active Ingredient(s): CARBOplatin URL for Additional Product Information: https://eugia.com/products/ Address: 279 Princeton-Hightstown Road City: East Windsor Key Contact: Phone Number: 888-238-7880 Product Therapeutic Classification: ANTINEOPLASTIC				Application: ANDA 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: Eugia US Customer Service Number: 888-238-7880 Group E-mail: CustomerService@EugiaUS.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: 30 Months Initial shelf life at launch (if different): Months																																																													
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION																																																													
The product is? a legend device? No if yes, enter class # a product kit? No if yes, list NDCs of component parts reverse numbered? co-licensed? No latex-free? Yes preservative-free? Yes 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:		Is the Product... Is the Product... Orphan Drug Status Direct-Ship Only FDA Approval Status Allergens Present Country of Origin Is this product covered under the Trade Agreements Act (TAA)?		Size: 1 Vial Strength: 450 mg per 45 mL (10 mg/mL) Dosage Form: Injection (Liquid) Product Shape: Vial Pack Product Color: Product Imprint:																																																													
FOR GENERIC DRUG PRODUCTS				ORDER INFORMATION																																																													
I. Orange Book Rating: AP II. Generic Equivalent to What Brand?: PARAPLATIN®				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? Each Inner/ Carton/ Pack 1 Case																																																													
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION				PHARMACY ORDER / BILL UNIT																																																													
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.				Rec. sell unit to customer? 1 Vial (Write-in, e.g. 1 Vial) HCP/CS J-Code: Rx billing unit to pharmacy: ☒ Each ☐ Gram ☐ Milliliter																																																													
GTIN AND HIBCC PRODUCT INFORMATION				ITEM AND PACKING INFORMATION																																																													
<table border="1"><thead><tr><th>Saleable Unit of Measure</th><th>RFID tag(Y/N)</th><th>Saleable Quantity</th><th>HIBCC</th><th>GTIN-14</th><th>Unit of Use GTIN-14</th></tr></thead><tbody><tr><td>☒ Item/Each</td><td></td><td>1</td><td></td><td>00355150335015</td><td></td></tr><tr><td>☒ Box/ Carton/ Bundle/ Inner Pack</td><td></td><td>24</td><td></td><td>50355150335010</td><td></td></tr><tr><td>☒ Case</td><td></td><td></td><td></td><td>70355150335014</td><td></td></tr><tr><td>☐ Pallet</td><td></td><td></td><td></td><td></td><td></td></tr></tbody></table>				Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14	☒ Item/Each		1		00355150335015		☒ Box/ Carton/ Bundle/ Inner Pack		24		50355150335010		☒ Case				70355150335014		☐ Pallet						<table border="1"><thead><tr><th>Item/Each:</th><th>Weight Lbs.</th><th>Dimensions (US msmts.) Depth</th><th>Width</th><th>Height</th><th>Volume (Cube)</th><th>Saleable # Pieces</th></tr></thead><tbody><tr><td>Box/ Carton/ Bundle/ Inner Pack:</td><td>0.37399</td><td>2.559</td><td>2.559</td><td>5.1181</td><td>33.515781</td><td>1</td></tr><tr><td>Case:</td><td>11.76086</td><td>12.0078</td><td>9.4488</td><td>13.3858</td><td>1518.7435</td><td>24</td></tr><tr><td>Pallet:</td><td>804.409</td><td>48</td><td>40</td><td>57.67</td><td>110726.4</td><td>1536</td></tr></tbody></table>				Item/Each:	Weight Lbs.	Dimensions (US msmts.) Depth	Width	Height	Volume (Cube)	Saleable # Pieces	Box/ Carton/ Bundle/ Inner Pack:	0.37399	2.559	2.559	5.1181	33.515781	1	Case:	11.76086	12.0078	9.4488	13.3858	1518.7435	24	Pallet:	804.409	48	40	57.67	110726.4	1536
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COST INFORMATION				WHOLESALE USE ONLY:																																																													
Regular Cost Invoice Cost (WAC) (\$) \$55.00 As of date: 7/13/2026				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.

See new p. 3 for Designated Drop Ship Only.

Signature:

Narender Chamala



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? ☐ 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:

- ☐ 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:

Release DATE

SDS Hazard Classification

- ☐ 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? ☐ Yes
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

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

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit: ☐ Yes

URL/Link to returns policy: <https://eugiaus.com/policies/return-policy/>

Special regulations or returns requirements for this product in certain states?

If so, which states? Other requirements? Comments?



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

Version 2024

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?



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

Version 2024

Introduction Type: Post Launch Change

☒ Final Version

Date: 7/13/2026

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: Eugia US LLC				Application: ANDA			
Application Number for NDA/ANDA/BLA; PMA/510(k): 205487							
Medical Device Class, if applicable:							
DUNS: 968961354							
Proprietary Name (If Applicable) and Established Name: CARBOplatin Injection, USP							
Selling Unit NDC: 55150-386-01				Unit of Use NDC: 55150-386-01			
UDI				UPC: 355150386017			
CVX Code:				MVX Code:			
Description: CARBOplatin Injection, USP 600mg per 60mL (10mg/mL) [MDV]							
Active Ingredient(s): CARBOplatin Injection, USP							
URL for Additional Product Information: https://eugiaus.com/products/							
Address: 279 Princeton-Hightstown Road				Address 2:			
City: East Windsor				State: NJ			
Key Contact:				Zip: 08520			
Phone Number: 888-238-7880				Email:			
Product Therapeutic Classification: ANTINEOPLASTIC				Fax:			
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is?		Is the Product...		Size:		1 Vial	
a legend device?		Is the Product...		Strength:		600 mg per 60 mL (10 mg/mL)	
if yes, enter class #		Orphan Drug Status		Dosage Form:		Injection (Liquid)	
a product kit?				Product Shape:		Vial Pack	
if yes, list NDCs of component parts		FDA Approval Status		Product Color:			
reverse numbered?				Product Imprint:			
co-licensed?		Allergens Present					
latex-free?							
preservative-free?							
correctional institution block?		Country of Origin					
opioid?							
Cannabinoid?							
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:							
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?: Paraplatin Injection							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer?				GLN:			
Is product exempt from DSCSA?							
If yes, select exemption:				GCP:			
Other exemption - Write in:							
Is product repackaged?				If yes, was original product purchased direct from mfr?			
Is product sold by manufacturer's exclusive distributor?				Provide source manufacturer for repackaged product			
Has FDA granted waiver/exception/exemption for product?							
If yes, attach documentation from FDA.							
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure		RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14	
☒ Item/Each			1		00355150386017		
☒ Box/ Carton/ Bundle/ Inner Pack					50355150386012		
☒ Case			24		70355150386016		
☒ Pallet							
ITEM AND PACKING INFORMATION							
	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces	
		Depth	Width	Height			
Item/Each:	0.4046	2.559	2.559	5.1181	33.515781	1	
Box/ Carton/ Bundle/ Inner Pack:							
Case:	12.4955	12.0078	9.4488	13.3858	1518.7435	24	
Pallet:	851.4901	48	40	57.67	110726.4	1536	
COST INFORMATION							
Regular Cost				WHOLESALE USE ONLY:			
Invoice Cost (WAC) (\$)				Vendor #:			
				Whsl. Code #:			
As of date: 7/13/2026				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:

Narender Chamala



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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?

Yes

b. CA Prop. 65 Carcinogen or Reproductive Toxicant?

No

Is the product a CA Prop 65 carcinogen?

Yes

Is the product a CA Prop 65 reproductive toxicant?

No

Does the product label bear a CA Prop 65 warning?

c. Contact Hazard?

No

d. Does this product require special clean-up instructions?

No

(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP?

No

Is this product regulated for shipment by DOT?

No

(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?

Is this product regulated for shipment by IATA?

No

(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?

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:

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?

Yes

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

Comments / Details: (For example, iPledge program?)

REMS:

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:

Yes

URL/Link to returns policy:

<https://eugiaus.com/policies/return-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?