



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

Version 2024		Introduction Type: <input type="checkbox"/> Post Launch Change		<input type="checkbox"/> Final Version		Date: 28.05.24	
<b>PRODUCT INFORMATION</b>						<b>SPECIAL HANDLING AND STORAGE REQUIREMENTS*</b>	
Company Name: Eugia US LLC (f/k/a AuroMedics Pharma LLC)				Application: ANDA		<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
Application Number for NDA/ANDA/BLA; PMA/510(k): 216939						Temperature Range: Cold – between 2 and 8 C (36° – 46° F)	
Medical Device Class, if applicable:						Other Temperature Range Requirement (write in):	
DUNS: 968961354						Notes: DO NOT FREEZE	
Proprietary Name (If Applicable) and Established Name: Carboprost Tromethamine Injection USP						Is this product to be shipped to customers on ice? <input type="checkbox"/> Yes	
Selling Unit NDC: 55150-459-10				Unit of Use NDC: 55150-459-01		Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No	
UDI				CVX Code:			
Description: Carboprost Tromethamine Injection USP (SDV), 250 mcg/mL				UPC: 355150459100			
Active Ingredient(s): Carboprost Tromethamine USP				MVX Code:			
URL for Additional Product Information: EugiaUS.com				Address 2:			
Address: 279 Princeton-Hightstown Road				NJ		Zip: 08520	
City: East Windsor				State: NJ			
Key Contact:				Email:			
Phone Number: 888-238-7880				Fax: 732-355-9449			
Product Therapeutic Classification: OXYTOCIC AGENT							
<b>ADDITIONAL PRODUCT INFORMATION</b>				<b>PRODUCT DESCRIPTION INFORMATION</b>			
The product is?		Is the Product...		Size:		10 x 1 mL Single-Dose Vials	
a legend device? <input type="checkbox"/> No		Is the Product... <input type="checkbox"/> Neither		Strength:		250 mcg per mL	
if yes, enter class #		Orphan Drug Status		Dosage Form:		Solution	
a product kit? <input type="checkbox"/> No		FDA Approval Status		Product Shape:		Vial Pack	
if yes, list NDCs of component parts				Product Color:		clear, colorless	
reverse numbered? <input type="checkbox"/> No		Allergens Present		Product Imprint:			
co-licensed? <input type="checkbox"/> No							
latex-free? <input type="checkbox"/> Yes		Country of Origin				India	
preservative-free? <input type="checkbox"/> No		Is this product covered under the Trade Agreements Act (TAA)?				<input type="checkbox"/> No	
correctional institution block? <input type="checkbox"/> No							
opioid? <input type="checkbox"/> No							
Cannabinoid? <input type="checkbox"/> No							
If Unit Dose, is item bar coded to unit dose for hospital scanning?							
If Unit Dose, indicate NDC here:							
<b>FOR GENERIC DRUG PRODUCTS</b>							
I. Orange Book Rating: AP				Authorized Generic <input type="checkbox"/> *If Authorized Generic, other section fields are not applicable			
II. Generic Equivalent to What Brand?: Hemabate® (carboprost tromethamine) injection USP, 250 mcg/mL [Single-Dose Ampoule] manufactured by Pfizer Inc.,							
<b>DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION</b>							
Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes				GLN:			
Is product exempt from DSCSA? <input type="checkbox"/> No				GCP:			
If yes, select exemption:				If yes, was original product purchased direct from mfr? <input type="checkbox"/>			
Other exemption - Write in:				Provide source manufacturer for repackaged product			
Is product repackaged? <input type="checkbox"/> No							
Is product sold by manufacturer's exclusive distributor? <input type="checkbox"/> No							
Has FDA granted waiver/exception/exemption for product? <input type="checkbox"/>							
If yes, attach documentation from FDA.							
<b>GTIN AND HIBCC PRODUCT INFORMATION</b>							
Saleable Unit of Measure		RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14	
<input checked="" type="checkbox"/> X	Item/Each		10		00355150459100		
	Box/ Carton/Bundle/Inner Pack				60355150459102		
	Case		240		80355150459106		
	Pallet		43200				
<b>ORDER INFORMATION</b>							
Unit of Sale				What is the NDC selling unit?			
<input checked="" type="checkbox"/> x	Bottle			1 Box of 10 Vials			
	Box/ Carton			(Write-in, e.g. 1 Box of 10 Vials)			
	Ampule			Minimum order quantity? <input type="checkbox"/> Yes			
	Glass						
	Tube			If Yes, how many of which package type?			
	Vial Liquid Sgl			<input type="checkbox"/> Each			
	Vial Liquid Multi			<input type="checkbox"/> Inner/ Carton/ Pack			
	Vial Powder Sgl			<input type="checkbox"/> Case			
	Vial Powder Multi						
	Other: Write In						
<b>PHARMACY ORDER / BILL UNIT</b>							
Rec. sell unit to customer? 10 Vials				Rx billing unit to pharmacy:			
(Write-in, e.g. 1 Vial)				<input checked="" type="checkbox"/> x Each			
HCPCS J-Code:				<input type="checkbox"/> Gram			
				<input type="checkbox"/> Milliliter			
<b>ITEM AND PACKING INFORMATION</b>							
	Weight Lbs.	Dimensions (US msmts.)	Volume (Cube)	Saleable #			
	Depth	Width	Height	Pieces			
Item/Each:	0.17636	3.54	1.38	1.77	8.647	10	
Box/ Carton/Bundle/ Inner Pack:					0		
Case:	5.335	8.4645	6.8897	6.8897	401.79	240	
Pallet:	993.293	48	40	46.34	88972.8	43200 vials	
<b>COST INFORMATION</b>				<b>WHOLESALE USE ONLY:</b>			
Regular Cost				Vendor #:			
Invoice Cost (WAC) (\$)				Whsl. Code #:			
As of date: 6/6/2023				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: D.Venkata Surender Reddy							



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Version 2024

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION			
<b>Is this product (check all that apply):</b>			
a. Cytotoxic?	<input type="text" value="No"/>		
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	<input type="text" value="No"/>		
Is the product a CA Prop 65 carcinogen?	<input type="text" value="No"/>		
Is the product a CA Prop 65 reproductive toxicant?	<input type="text" value="No"/>		
Does the product label bear a CA Prop 65 warning?	<input type="text" value="No"/>		
c. Contact Hazard?	<input type="text" value="No"/>		
d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)	<input type="text" value="No"/>		
e. Does the product contain DEHP?	<input type="text" value="No"/>		
<b>Is this product regulated for shipment by DOT?</b> (if yes, answer a-e below and provide SDS)			
a. UN/Identification Number	<input type="text"/>		
b. Proper Shipping Name	<input type="text"/>		
c. DOT Hazard Class	<input type="text"/>		
d. Packing Group	<input type="text"/>		
e. Inhalation Hazard?	<input type="text" value="No"/>		
<b>Is this product regulated for shipment by IATA?</b> (if yes, answer a-e below and provide SDS)			
a. UN/Identification Number	<input type="text"/>		
b. Proper Shipping Name	<input type="text"/>		
c. DOT Hazard Class	<input type="text"/>		
d. Packing Group	<input type="text"/>		
e. Inhalation Hazard?	<input type="text" value="No"/>		
<b>Is the product restricted for air shipment? If so, indicate restriction:</b>			
<input type="checkbox"/> Passenger	<input type="text" value="No"/>		
<input type="checkbox"/> Cargo			
<input type="checkbox"/> Passenger & Cargo			
<b>Is this a reportable quantity?</b> <input type="text" value="No"/>			
RQ Threshold: <input type="text"/>			
<b>Is this a marine pollutant?</b> <input type="text" value="No"/>			
<b>Is this product shipped utilizing an authorized DOT exception or Special Permit?</b> (if yes, identify method below)			
<input type="checkbox"/> Limited Quantity	<input type="text"/>		
<input type="checkbox"/> Consumer Commodity, ORM-D			
<input type="checkbox"/> Small Quantity (49 CFR 173.4)			
<input type="checkbox"/> Special Permit; DOT-SP			
<input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101);			
SP# <input type="text"/>			
<b>ADD'L STORAGE INFORMATION</b>			
<b>Is the Product...</b>			
Controlled Substance?	<input type="text" value="No"/>	Controlled Substance Code	<input type="text"/>
Controlled by State(s)?	<input type="text" value="No"/>	Listed Chemical (List I or II)	<input type="text" value="No"/>
ARCOS Reportable?	<input type="text" value="No"/>	If yes, indicate which:	<input type="text"/>
Schedule No.	<input type="text"/>	Is it a scheduled listed chemical product?:	<input type="text" value="No"/>
<b>CLASS OF TRADE RESTRICTION:</b>			
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices		<input type="text" value="Yes"/>	
Restricted to retail pharmacy only:		<input type="text" value="No"/>	
Restricted to hospital, clinics, and physician offices only:		<input type="text" value="No"/>	
Restricted from US territories? (explain in comments)		<input type="text" value="No"/>	
Comments: <input type="text"/>			
<b>SDS Hazard Classification</b>			
<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive		
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer		
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard		
Does the product have an Aerosol class? If yes, identify NFPA Storage Level:		<input type="text" value="No"/>	
NFPA Storage Level:		<input type="text"/>	
Is the product a NIOSH hazardous drug?		<input type="text" value="No"/>	
If yes, indicate which:		<input type="text"/>	
<b>Hazardous Waste Identification</b>			
EPA Hazardous Waste Code:		Waste Characteristics <input type="text"/>	
<b>REMS or REGISTRY RESTRICTIONS</b>			
<b>Is there a REMS on this product?</b>		<input type="text" value="No"/>	
If Yes, is it managed with a pharmacy registry?		<input type="text"/>	
Website URL:		<input type="text"/>	
<b>Med Guide Required</b>		<input type="text" value="No"/>	
<b>Limited Distribution Requirement</b>		<input type="text" value="No"/>	
Comments / Details: (For example, iPledge program?)		<input type="text"/>	
<b>REMS:</b>		<input type="text" value="No"/>	
REMS Program Manager Name:		Phone: <input type="text"/>	
Supplier Manages REMS registry exclusively:		<input type="text"/>	
Wholesale distributor support:		<input type="text"/>	
Provider Name:		DEA #: <input type="text"/>	
Site Enrollment Number assigned by Supplier:		NCPDP#: <input type="text"/>	
NPI #: <input type="text"/>			
Comments		<input type="text"/>	
<b>Registry:</b>		<input type="text" value="No"/>	
Registry Program Contact Name:		Phone: <input type="text"/>	
Comments		<input type="text"/>	
<b>RETURN INSTRUCTIONS</b>			
Contact tel. # if product received damaged:		<input type="text"/>	
Is product returnable for credit:		<input type="text" value="Yes"/>	
URL/Link to returns policy:		<input type="text" value="https://eugiaus.com/policies/return-policy/"/>	
Special regulations or returns requirements for this product in certain states?		<input type="text" value="No"/>	
If so, which states? Other requirements? Comments:		<input type="text"/>	
<b>MISCELLANEOUS NOTES and/or Image of Product Barcode:</b>			
<input type="text"/>			



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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
<p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="text"/></p> <p>b. Autofax <input type="text"/></p> <p>c. Fax <input type="text"/></p> <p>d. Phone only <input type="text"/></p> <p>e. Supplier Web Site only <input type="text"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <input type="text"/></p>	<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="text"/></p> <p>Ships for second day receipt: <input type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="text"/></p>
<p><b>Expedited Freight Charges or Other Designated Drop Ship Fees:</b></p> <p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p><b>Overnight and Priority Overnight PO Processing</b></p> <p><b>Overnight receipt available:</b> <input type="text"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p><b>Priority Overnight receipt available:</b> <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="text"/></p> <p>Other fees apply: <input type="text"/></p>
<p><b>Class of Trade Restriction:</b></p> <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="text"/></p> <p>Restricted to retail pharmacy only: <input type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="text"/></p> <p>Restricted from US territories? (explain in comments) <input type="text"/></p> <p>Comments: <input type="text"/></p>	
<p><b>Other Data Information Required to Process PO:</b></p> <p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p><b>Return Instructions</b></p> <p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="text"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="text"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>
<p><b>Miscellaneous Notes:</b></p> <p><input type="text"/></p>	<p><b>ADDITIONAL INFORMATION</b></p> <p>Is product order for scheduled patient procedure? <input type="text"/></p> <p>Is product order for restocking purposes? <input type="text"/></p>