



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

Version 2024		Introduction Type: New Item		Final Version		Date: 9/8/2025																																															
PRODUCT INFORMATION						SPECIAL HANDLING AND STORAGE REQUIREMENTS*																																															
Company Name: MILLA PHARMACEUTICALS INC Application Number for NDA/ANDA/BLA; PMA/510(k): A212676 Medical Device Class, if applicable: DUNS: 119319487 Proprietary Name (If Applicable) and Established Name: Selling Unit NDC: 81284-0611-10 Unit of Use NDC: 81284-0611-00 UPC: 381284611107 CVX Code: MVX Code: Description: Tranexamic Acid Injection, USP 100 mg/mL 10mL x 10 vials Active Ingredient(s): Tranexamic Acid URL for Additional Product Information: Address: 1310 Highway 96E City: White Bear Lake Key Contact: Siddharth Nirmal Phone Number: +1 302 946 0117 Product Therapeutic Classification: State: MN Address 2: Suite 104A Email: siddharth.nirmal@aforalpharma.com Fax: Zip: # 55110						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): Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F) [see USP Controlled Room] 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: DL-QA GPI Pharma Number: Group E-mail: qa@gpipharma.ie c. Special regulations for product in any states? Special returns requirements for this product? No d. Store product (unit of sale) upright? No Protect product (unit of sale) from light? No e. Shelf life: 24 Months Initial shelf life at launch (if different): 24 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? Yes If Unit Dose, indicate NDC here:				Is the Product... Direct-Ship Only Is the Product... Unit of Use Orphan Drug Status: FDA Approval Status: Allergens Present: Country of Origin: India Is this product covered under the Trade Agreements Act (TAA)? No				Size: 10mL Strength: 1000mg/10mL Dosage Form: Injectable Product Shape: NA Product Color: NA Product Imprint: NA																																													
FOR GENERIC DRUG PRODUCTS						ORDER INFORMATION																																															
I. Orange Book Rating: AP II. Generic Equivalent to What Brand?: Cyklokapron						Unit of Sale <table border="1" style="width:100%; border-collapse: collapse;"><tr><td>☒</td><td>Bottle</td></tr><tr><td>☒</td><td>Box/ Carton</td></tr><tr><td>☐</td><td>Ampule</td></tr><tr><td>☐</td><td>Glass</td></tr><tr><td>☐</td><td>Tube</td></tr><tr><td>☐</td><td>Vial Liquid Sgl</td></tr><tr><td>☐</td><td>Vial Liquid Multi</td></tr><tr><td>☐</td><td>Vial Powder Sgl</td></tr><tr><td>☐</td><td>Vial Powder Multi</td></tr><tr><td>☐</td><td>Other: Write In</td></tr></table> What is the NDC selling unit? 1 box of 10 vials (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity? Yes If Yes, how many of which package type? <table border="1" style="width:100%; border-collapse: collapse;"><tr><td> </td><td>Each</td></tr><tr><td> </td><td>Inner/ Carton/ Pack</td></tr><tr><td> 1 </td><td>Case</td></tr></table>		☒	Bottle	☒	Box/ Carton	☐	Ampule	☐	Glass	☐	Tube	☐	Vial Liquid Sgl	☐	Vial Liquid Multi	☐	Vial Powder Sgl	☐	Vial Powder Multi	☐	Other: Write In		Each		Inner/ Carton/ Pack	1	Case																				
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Rec. sell unit to customer? 1 box of 10 vials (Write-in, e.g. 1 Vial) HCP/CS J-Code: Rx billing unit to pharmacy: <table border="1" style="width:100%; border-collapse: collapse;"><tr><td> </td><td>Each</td></tr><tr><td> </td><td>Gram</td></tr><tr><td><input checked="" type="text" value="x"/></td><td>Milliliter</td></tr></table>							Each		Gram	<input checked="" type="text" value="x"/>	Milliliter																																										
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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? Yes Has FDA granted waiver/exception/exemption for product? No If yes, attach documentation from FDA. GLN: 0381284000000 GCP: If yes, was original product purchased direct from mfr? No Provide source manufacturer for repackaged product																																																					
GTIN AND HIBCC PRODUCT INFORMATION																																																					
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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:																																																					



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?

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?

Yes

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

Yes

(If yes, attach SDS with special instructions.)

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?

Yes

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?

Yes

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:

SDS Hazard Classification

☐ Organic

☐ Inorganic

☐ Steroid/Androgen

☐ Corrosive

☐ Oxidizer

☒ Contact Hazard

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

NFPA Storage Level:

Is the product a NIOSH hazardous drug?

If yes, indicate which:

No

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

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:

Registry Program Contact Name:

Phone:

Comments

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

773-541-3317

Is product returnable for credit:

Yes

URL/Link to returns policy:

www.millapharmaceuticals.com

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	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?