

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

						Introduction Type	New Item		Final Version			Date:	9/8/2	2025
			PRODUCT INFORMAT	TION					SPECIAL HAND	LING AND STOR	AGE REQUIR	EMENTS*		
Company Name:	MILLA PHARMAC	EUTICALS INC				Application:	ANDA	a Temperatur	e - Indicate the USP temper	rature range for th	nis product			
Application Number for NDA/ANI						7466	7.11271	u. remperatur		Controlled Room -		and 25 C (68	– 77° F)	
Medical Device Class, if applicab		(,.						1						
DUNS:	119319487				1				Other Temperature Range R	equirement				
Proprietary Name (If Applicable) a		me:						1	(write in)	oquilolliolik				
Selling Unit NDC:	81284-0411-10		Unit of Use NDC:		81284-0411-00	UPC: 38	284411103	-	Notes					
UDI			CVX Code:			MVX Code:		-	110.00					
	Dilember of the second	. \$4						-	La Alula manada ak ka la a alulama ad		- 0		NI.	
Description:	Dinydroergotamin	e Mesylate Injection, U	SP 1mg/mL 10 amps						Is this product to be shipped			ļ	No	i
Active Ingredient(s):		Dihydroergotamine M	dete					41	Is this product to be shipped	to customers on a	ry ice?	J	No	1
Active ingredient(s):		Dinydroeigotamine ivi	esylate					h Contact for	temperature excursion que	otiona				
URL for Additional Product Inform	ation:							b. Contact for	Name:		DL-QA GPI F	harma		
Address:	1310 Highway 96	-			I	Address 2: Su	te 104A	-	Number:		DE 00.0	nama		
City:	White Bear Lake				State:				Group E-mail:		qa@gpipha	rma.ie		
Key Contact:	Siddharth Nirmal				Email:						4-0-1			
Phone Number:	+1 302 946 0117				Fax:			c. Special regi	ulations for product in any	states?		Į.	No	i
Product Therapeutic Classification									Special returns requirements				No	i
. roudet morapouno ciacomouno.									opoolar rotamo roquiromonto	ror and product.		I		
	ADDITI	ONAL PRODUCT INFO	RMATION			PRODUCT DES	CRIPTION INFORMATION	d Store produ	uct (unit of sale) upright?			F	No	l .
The much set is 2			Is the Product	Direct-Ship	Only			1	, , , ,	a) fuama limbt?		I.	Yes	1
The product is? a legend device?		No	Is the Product	Unit of Use	Ciny		1mL	e. Shelf life:	Protect product (unit of sal	e, nom ngntr			Yes 24	Months
if yes, enter class #		INU	Orphan Drug Status	Crist or ose		Size:	IIIL		Initial shelf life at launch (if	different).			24	Months
a product kit?		No	Orphan Drug Status				1mg/mL		miliai shen me at launch (ii	umerent).		I		Wionins
if yes, list NDCs of		140	FDA Approval Status			Strength:	mg/mc			ORDER INFORM	ATION			
component parts			. Drivippi oral otatao				Injectable							
reverse numbered?		No				Dosage Form:	,		Unit of Sale		What is the I	NDC selling	unit?	
co-licensed?		No	Allergens Present						Bottle		1 box of 10 a	mpules		
latex-free?		Yes				Product Shape:	NA		x Box/Carton		(Write-in, e.g	g. 1 Box of 10	Vials)	
preservative-free?		Yes				Product Snape.			Ampule					
correctional institution block?		No				Product Color:	NA		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Froduct Color.			Tube				_	
Cannabinoid?		No	Country of Origin	France		Product Imprint:	NA		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for					. roudot imprinti			Vial Liquid Multi		If Yes, how r		h package t	ype?
hospital scanning?		No	Is this product covered ur						Vial Powder Sql			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (T.	AA)?	Yes				Vial Power Multi			Inner/Carton/	Pack	
								<u>]                                    </u>	Other: Write In			Case		
			OR GENERIC DRUG PRO	ADUCTO										
			011 021121110 D1100 1 110	DDUCIS										
		'		DDUCIS					PIL	DM A OV ODDED	/ DULL LINET		$\overline{}$	
		'		_	Aut		Authorized Generic, other			ARMACY ORDER				
I. Orange Book Rating:	AP				Aut		Authorized Generic, other tion fields are not applicable	Rec. sell unit t	to customer?	ARMACY ORDER	/ BILL UNIT Rx billing ur		cy:	
I. Orange Book Rating: II. Generic Equivalent to What Brai		D.H.E 45 - N018885			Aut			1 bo	to customer? ox of 10 ampules	ARMACY ORDER		Each	су:	
		D.H.E 45 - N018885						1 bo (Write-in, e.g.	to customer? ox of 10 ampules 1 Vial)	ARMACY ORDER	Rx billing ur	Each Gram	су:	
		D.H.E 45 - N018885	CHAIN SECURITY ACT (E					1 bo	to customer? ox of 10 ampules 1 Vial)	ARMACY ORDER		Each	ıcy:	
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II. Generic Equivalent to What Brain Does supplier meet DSCSA definiting product exempt from DSCSA?	nd?:	D.H.E 45 - N018885	CHAIN SECURITY ACT (E		RMATION GLN:	sec		1 bo (Write-in, e.g.	to customer? ox of 10 ampules 1 Vial) le:	AND PACKING IN	Rx billing un x	Each Gram Milliliter		Saloablo #
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II. Generic Equivalent to What Brain Does supplier meet DSCSA definit Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	nd?:	D.H.E 45 - N018885	CHAIN SECURITY ACT (I Yes No		RMATION GLN: GCP:	0381284000000	tion fields are not applicable	1 bd (Write-in, e.g. HCPCS J-Cod	to customer? ox of 10 ampules 1 Vial) le: ITEM Weight Lbs.	AND PACKING IN Dimensio Depth	Rx billing ur x  IFORMATION ons (US msm Width	Each Gram Milliliter  its.) Height	Volume (Cube)	Pieces
II. Generic Equivalent to What Brain Does supplier meet DSCSA definit Is product exempt from DSCSA?  If yes, select exemption:	nd?: tion of manufactur	D.H.E 45 - N018885  DRUG SUPPLY er?	CHAIN SECURITY ACT (E		RMATION GLN: GCP:	0381284000000 ginal product purchas	tion fields are not applicable	1 bo (Write-in, e.g.	to customer? ox of 10 ampules 1 Vial) le:	AND PACKING IN	x IFORMATION	Each Gram Milliliter  its.) Height	Volume	
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## **Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)**

#### Version 2024

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL H	AZARD CLASSIFICATION and TRANSPORTATION				
Is this product (check all that apply):					
a. Cytotoxic?	SDS Hazard Classification				
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?					
Is the product a CA Prop 65 carcinogen?  Is the product a CA Prop 65 reproductive toxicant?  Yes	Organic Corrosive Inorganic Oxidizer				
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen x Contact Hazard				
2000 the product laber soul a control of the laming.	conductivation				
c. Contact Hazard?	Does the product have an Aerosol class? If yes,				
d. Does this product require special clean-up instructions?	identify NFPA Storage Level:				
(If yes, attach SDS with special instructions.)	NFPA Storage Level:				
e. Does the product contain DEHP?					
Is this product regulated for shipment by DOT?	Is the product a NIOSH hazardous drug?				
(if yes, answer a-e below and provide SDS)	If yes, indicate which:				
a. UN/Identification Number b. Proper Shipping Name					
c. DOT Hazard Class	Hazardous Waste Identification				
d. Packing Group					
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics				
Is this product regulated for shipment by IATA?					
(if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS				
a. UN/Identification Number	Latin and DEMO, and this conduction				
b. Proper Shipping Name c. DOT Hazard Class	Is there a REMS on this product?  If Yes, is it managed with a pharmacy registry?				
d. Packing Group	Website URL:				
e. Inhalation Hazard?					
Is the product restricted for air shipment? If so, indicate restriction:	Med Guide Required				
Passenger	Limited Distribution Requirement				
Cargo	Comments / Details: (For example, iPledge program?)				
Passenger & Cargo					
Is this a reportable quantity? No RQ Threshold:	REMS:  REMS Program Manager Name:  Phone:				
Is this a marine pollutant?	REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively:				
Is this product shipped utilizing an authorized DOT exception or Special Permit?	Wholesale distributor support:				
No (if yes, identify method below)	Provider Name: DEA #:				
Limited Quantity	Site Enrollment Number assigned NCPDP#:				
Consumer Commodity, ORM-D	by Supplier: NPI #:				
Small Quantity (49 CFR 173.4) Special Permit; DOT-SP	Comments				
Special Provision (listed in Column 7 of 49 CFR 172.101);	Commence				
SP#	Registry:				
	Registry Program Contact Name: Phone:				
ADD'L STORAGE INFORMATION	Comments				
Is the Product					
Controlled Substance?  No Controlled Substance Code	RETURN INSTRUCTIONS				
Controlled by State(s)? No Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which:	Contact tel. # if product received damaged: 773-541-3317				
Schedule No. Is it a scheduled listed chemical product?: No	Is product returnable for credit:  Yes				
CLASS OF TRADE RESTRICTION:	URL/Link to returns policy:				
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes	www.millapharmaceuticals.com				
Restricted to retail pharmacy only:  No					
Restricted to hospital, clinics, and physician offices only:  No	Special regulations or returns requirements for this product in certain states?				
Restricted from US territories? (explain in comments)  No	If so, which states? Other requirements? Comments?				
Comments:	i				
MISCELLAN	EOUS NOTES and/or Image of Product Barcode:				



## **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:	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:	Overnight and Priority Overnight PO Processing					
Expedited freight fees billed with each order:  Drop Ship service fee billed with each order:  Drop Ship miscellaneous fees billed:  Comments:	Overnight receipt available:  PO Receipt cut off time:  Days of week overnight is available:  Monday Tuesday Wednesday Thursday Friday					
	Priority Overnight receipt available:					
Class of Trade Restriction:	PO Receipt Cut off time:					
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:	Saturday Overnight receipt available:  PO Receipt Cut off time:  Phone: Fax: EDI:  Overnight Fees apply: Other fees apply:					
Other Data Information Required to Process PO:	Return Instructions					
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:  Miscellaneous Notes:	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?					
	ADDITIONAL INFORMATION					
	Is product order for scheduled patient procedure? Is product order for restocking purposes?					