

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

Version 2024						Introduction Type:	New Item	x	Final Version			Date:	12/19	9/2024
			PRODUCT INFORMA	TION					SPECIAL HAN	IDLING AND STOP	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. AND						ANDA	a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/AN	DA/BLA; PMA/510(	k): 217566				NDA 505(b) Type:	NOT APPLICABLE	Temper	ature Range	Controlled Room	- between 20	and 25 C (68	° – 77° F)	
Medical Device Class, if applicat	ble:													
DUNS:	11-856-3719								emperature Range I	Requirement				
Proprietary Name (If Applicable) a		me: Dicyclor	mine Hydrochloride Tablets	, USP 20 mg		1150			rite in)					
Selling Unit NDC:	31722-079-01		Unit of Use NDC:			UPC: 331 MVX Code:	722079013	Notes						
UDI			CVX Code:			WIVA Code.								
Description:	Dicyclomine Hydro	chloride Tablets, USF	20 mg						roduct to be shipped				No	-
Active Ingredient(s):		Dicyclomine hydroch	loride LISP					is this p	roduct to be shipped	a to customers on a	ary ice?		No	
Active ingredient(3).		Dicyclonnine nydroch						b. Contact for tempera	ature excursion qu	estions:				
URL for Additional Product Inform	nation:	www.camberpharma.	.com					Name:			Soma Raju			
Address:	800 Centennial Av	e, Suite 1				Address 2:		Numbe	r:		732-529-042	23		
City:	Piscataway				State:		<b>o:</b> 08854	Group	E-mail:		somaraju@l	neterousa.cor	<u>n</u>	
Key Contact:	Customer Service				Email:	customerservice@carr	nberpharma.com							-
Phone Number:	1-866-827-3647	A			Fax:	732-562-8788		c. Special regulations					No	-
Product Therapeutic Classification	n:	Antispasmodic and a	nticholinergic (antimuscarir	nic) agent				Special	returns requirement	ts for this product?			No	
		ONAL PRODUCT INF				PRODUCT DESC	CRIPTION INFORMATION	d. Store product (unit	of colo) upright?				No	1
	ADDITIC			Discus Ohio O		FRODUCT DESC								-
The product is? a legend device?		Na	Is the Product Is the Product	Direct-Ship Or Neither	niy		100 ct	e. Shelf life:	product (unit of sa	ale) from light?			No 24	Months
if yes, enter class #		No	Orphan Drug Status	Neither		Size:	100 Ct		helf life at launch (	if different).			24	Months
a product kit?		No	orphan brug otatus				20 mg	indu s	anen me at laanen (	in americiny.				months
if yes, list NDCs of			FDA Approval Status			Strength:	- 5			ORDER INFORM	NATION			
component parts						Dosage Form:	Unscored tablet							
reverse numbered?		No				Decagerenni		Unit of				NDC selling	unit?	
co-licensed?		No	Allergens Present				David fiel (and	X	Bottle		1 Bottle of 1		0 \ (' - 1 - )	
latex-free? preservative-free?		Yes Yes	Corn, Lact	ose, Casein		Product Shape:	Round, flat faced, beveled edge		Box/Carton Ampule		(vvrite-in, e	g. 1 Box of 1	u viais)	
correctional institution block?		No					Light blue to blue		Glass		Minimum o	rder quantity	2	Yes
opioid?		No				Product Color:	Light blue to blue		Tube			uor quantity	•	100
Cannabinoid?		No	Country of Origin	India		Product Imprint:	Debossed with 'V1' on one side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for					rioddet imprint.	and '44' on other side		Vial Liquid Multi				ch package f	type?
hospital scanning?			Is this product covered u						Vial Powder Sgl		24	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (1	AA)?	No				Vial Powder Multi Other: Write In			Inner/Carton Case	/Pack	
			FOR GENERIC DRUG PR	ODUCTO					Other. White in			Case		
			FOR GENERIC DRUG FR	000013										
					Au	uthorized Generic *If A	Authorized Generic, other		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB			- · · · ·			tion fields are not applicable	Rec. sell unit to custo	mer?		Rx hilling u	nit to pharma	acv.	
II. Generic Equivalent to What Bra		Bentyl										Each		
								(Write-in, e.g. 1 Vial)		-		Gram		
		DRUG SUPPLY	CHAIN SECURITY ACT (	DSCSA) INFOR	MATION			HCPCS J-Code:		_		Milliliter		
			N	_					1751	AND PACKING I				
Does supplier meet DSCSA definit Is product exempt from DSCSA?	tion of manufacture	er?	Yes	-	GLN:	0331722498975			ITEN	AND PACKING I	NFORMATIO	N		
			NO							_				
If yes, select exemption:					GCP:				Weight Lbs.		ions (US msr		Volume	Saleable #
Other exemption - Write in: Is product repackaged?			No		If yes was o	riginal product purchase	ba	Item/Each:		Depth	Width	Height	(Cube)	Pieces
Is product sold by manufacturer's	exclusive distribut	tor?	Yes		direct from m				0.09	1.57	1.57	3.12	7.69	1
Has FDA granted waiver/exception			No			ce manufacturer for rep	ackaged product	Box/Carton/Bundle/						
If yes, attach documentation from	m FDA.	·		-		•		Inner Pack:						
								Case:	2.4	9.75	6.75	4.25	279.70	24
		GTIN	AND HIBCC PRODUCT I	NFORMATION				Ballati						
Saleable Unit of Measure	RFID tag(Y/N)	Saleable	HIBCC		GTI	N-14	Unit of Use GTIN-14	Pallet:						
Salcable Onit of Measure		Quantity	TIDOC		011	11-14	Unit of Use Grint-14							
X Item/Each	N	1			003	31722079013								
Box/Carton/Bundle/Inner Pack								COS	ST INFORMATION			WHOLESALI	ER USE ONL	LY:
X Case	N	24			203	31722079017				-				
Pallet								Regular Cost			Vendor #:			
								Invoice Cost (WAC) (\$	5)	\$15.53	Whsl. Code			
								As of date:	10/1/2024		Fineline Co	ue:		
								no or uald.	.0/ 1/2024		4			
			Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza	ard letter, PACKAGE INSE	ERT, LABEL AND PHOTO OF P	RODUCT PACKAGING ar	nd BARCODE.					
*Please provide any additional info	ormation on page 2		Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza		ERT, LABEL AND PHOTO OF P	RODUCT PACKAGING ar Signatu						

## HDA🔾

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

Version 2024 For Designa	ted Drop Ship Only Products, Please Use Page 3					
MATERIAL HA	ZARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply): a. Cytotoxic? 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? Does the product label bear a CA Prop 65 warning? No	x     Organic     Corrosive       Inorganic     Oxidizer       Steroid/Androgen     Contact Hazard					
c. Contact Hazard? 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	Does the product have an Aerosol class? If yes, identify NFPA Storage Level:       No         NFPA Storage Level:       Image: Storage Level:         Is the product a NIOSH hazardous drug?       No					
(if yes, answer a-e below and provide SDS) a. UN/dentification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group	If yes, indicate which: Hazardous Waste Identification					
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics					
Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS) (if Unit for the North Context of the Nor	REMS or REGISTRY RESTRICTIONS					
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is there a REMS on this product? No If Yes, is it managed with a pharmacy registry? Website URL:					
Is the product restricted for air shipment? If so, indicate restriction:           Passenger           Cargo           Passenger & Cargo	Med Guide Required No Limited Distribution Requirement Comments / Details: (For example, iPledge program?)					
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)	REMS:     No       REMS Program Manager Name:     Phone:       Supplier Manages REMS registry exclusively:     Phone:       Wholesale distributor support:     DEA #:       Provider Name:     NCPDP#:       Site Enrollment Number assigned     NPI #:					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	Comments					
SP#ADD'L STORAGE INFORMATION	Registry:     No       Registry Program Contact Name:     Phone:       Comments					
Is the Product Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS					
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:         If           Schedule No.         Is it a scheduled listed chemical product?:         No	Contact tel. # if product received damaged:     1-866-827-3647       Is product returnable for credit:     Yes					
	URL/Link to returns policy:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes Restricted to retail pharmacy only: No	contact - customerservice@camberpharma.com Special regulations or returns requirements for this					
No         No           Restricted from US territories? (explain in comments)         No	Special regulations of returns requirements for this         product in certain states?         If so, which states? Other requirements? Comments?					
Comments:						
MISCELLANE	OUS 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       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:	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:
Phone:	Overnight and Drivity Overnight DO Broossing
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:         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:	PO Receipt Cut off time:       PO Receipt Cut off time:         Saturday Overnight receipt available:       PO Receipt Cut off time:         PO Receipt Cut off time:       Phone:         Order receipt method:       Phone:         Fax:       EDI:         EDI:       Covernight Fees apply:         Other fees apply:       Image: Covernight Fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	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?