

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

Version 2021						Introduction Ty	ype:	New Item		x Final Version			Date:	1/30	/2024
			PRODUCT INFORMA	TION						SPECIAL H	ANDLING AND STO	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA						ANDA	a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 216174							Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)								
Medical Device Class, if applicable:															
DUNS:	11-856-3719									Other Temperature Ran	ge Requirement	Excursions	permitted to 1	5° to 30°C (5	9° to 86°F)
Proprietary Name (If Applicable) a		ame: Palip	eridone Extended-Release T							(write in)					
Selling Unit NDC:	31722-317-30		Unit of Use NDC		31722-317-30		331722317306			Notes					
UDI			CVX Code:			MVX Code:			l l						
Description:	Paliperidone Exte	ended-Release Table	ets 1.5 mg							Is this product to be ship	ped to customers on	ice?		No	
									Is this product to be ship	ped to customers on	dry ice?		No		
Active Ingredient(s): Paliperidone, USP							1		_						
IND. Co. A. Children, Dr. Astronomy, Co.							b. Contact for temperature excursion questions:								
URL for Additional Product Inform Address:		www.camberpharm Ave (and) 800 Cente			1	Address 2:				Name: Number:		Soma Raju 732-529-042	22		
City:	Piscataway	Ave (and) 600 Cente	enniai Ave, Suite I		State:		Zip : 08854			Group E-mail:				m	
Key Contact:	Customer Service				customerservice@						somaraju@heterousa.com				
Phone Number:	1-866-827-3647				Fax:	732-562-8788			c. Special re	gulations for product in a	ny states?			No	1
Product Therapeutic Classification	n:	Atypical antipsych	otic							Special returns requirem	-			No	1
		,, ,,								.,					
	ADDIT	ONAL PRODUCT I	NFORMATION			PRODUCT DI	ESCRIPTION I	NFORMATION	d. Store prod	duct (unit of sale) upright	?			No	1
The product is?			Is the Product	Direct-Ship	Only				·	Protect product (unit o				No	i
a legend device?		No	Is the Product	Unit of Use	-	0:	30 ct		e. Shelf life:		,			24	Months
if yes, enter class #			Orphan Drug Status			Size:				Initial shelf life at laund	h (if different):				Months
a product kit?		No	· -	-		Strength:	1.5 mg								
if yes, list NDCs of			FDA Approval Status			Su engui.					ORDER INFORI	MATION			
component parts						Dosage Form:	Film Co	ated Tablet							
reverse numbered?		No								Unit of Sale			NDC selling	unit?	
co-licensed? latex-free?		No Yes	Allergens Present	Alaskal Anim	al Cuman		Daviad	cylindrical,		x Bottle Box/Carton		1 Bottle of 3		0 \ /:ala\	
preservative-free?		Yes	Lactose, Dairy, Corn,	ein, Whey, Dye		Product Shap	biconve			Ampule		(vvnie-in, e	.g. 1 Box of 1	o viais)	
correctional institution block?		No	ixemiet, Cas	eiii, wiley, Dye			Light he	eige to beige		Glass		Minimum o	rder quantity	12	Yes
opioid?		No				Product Color	r:	ige to beige		Tube			ruor quantity	•	103
Cannabinoid?		No	Country of Origin	USA		Boo door book	Printed w	ith "15" in black ink		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for		• •			Product Impri	int:			Vial Liquid Mu	ti	If Yes, how	many of whi	ich package	type?
hospital scanning?			Is this product covered	under the						Vial Powder S	Įl	24	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (TAA)?	Yes					Vial Power Mu			Inner/Cartor	n/Pack	
										Other: Write In			Case		
			FOR GENERIC DRUG PF	RODUCTS											
							*16 A	2			PHARMACY ORDER	/ DILL LINIT			
					Aut		*If Authorized	Jeneric, other ire not applicable	_		PHARMACY ORDER				
I. Orange Book Rating:	AB						Section neius a	пе погаррисавле	Rec. sell uni	t to customer?		Rx billing u	nit to pharm	acy:	
II. Generic Equivalent to What Bra	nd?:	Invega®							(Write-in, e.g	1 1 \/ial\			Each Gram		
		DRUG SUPP	LY CHAIN SECURITY ACT	(DSCSA) INFO	RMATION				(vviite-iii, e.g	j. i vidi)			Milliliter		
				(,											
Does supplier meet DSCSA defini	tion of manufactu	rer?	Yes		GLN:	0331722000000					EM AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			No												
If ves. select exemption:					GCP:						Dimens	ions (US msr	nts.)	Volume	Saleable #
Other exemption - Write in:									· I	Weight Lbs	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was ori	ginal product purch	hased		Item/Each:	0.075	1.55	1.55	3.15	7.57	1
Is product sold by manufacturer's			Yes		direct from mi						1.55	1.55	3.13	7.57	'
Has FDA granted waiver/exception		roduct?	No		Provide source	e manufacturer for	repackaged p	roduct	Box/Carton/i	Bundle/					
If yes, attach documentation from	m FDA.								Inner Pack:						
		CI	IN AND HIBCC PRODUCT I	NEODMATION					Case:	2.3	10	6.75	3.75	253.13	24
		- GI	IN AND HIBCC PRODUCT	NECKWATION					Pallet:						
Saleable Unit of Measure		Saleable Quantity	HIBCC		GTIN	I-1 <i>I</i>	Unit o	f Use GTIN-14	railet.						
X Item/Each	`	1	TIIDCC			1722317306		722317306							
Box/Carton/Bundle/Inner Pack										COST INFORMATION	N		WHOLESAL	ER USE ONL	.Y:
X Case		24			1033	1722317303				· · · · · · · · · · · · · · · · · · ·					
Pallet									Regular Cos	t	_	Vendor #:			
									Invoice Cost	(WAC) (\$)	\$65.00	Whsl. Code			
												Fineline Co	de:		
									As of date:	1/16/2024					
!			August convert CAFFTY D	ATA CHEET (O	DC) as non harra	dietter DACKACE!	INICEDE I ASS	I AND DUOTO OF P	LI DA CI	ACING and DADCORE		1			
*Please provide any additional inf	armatian an re	2	Attach copy of SAFETY D.	AIA SHEET (SI	or non nazar رحر				RODUCT PACK						
*Please provide any additional inf	ormation on page	۷.				See new p. 3 for D	vesignated Dr	op onip only.		Signature:					



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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? No	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? No 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? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP? No	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level:						
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	Is the product a NIOSH hazardous drug? If yes, indicate which:						
c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification						
e. Inhalation Hazard? Is this product regulated for shipment by IATA? No	EPA Hazardous Waste Code: Waste Characteristics						
(if yes, answer a-e below and provide SDS) a. UN/Identification Number	REMS or REGISTRY RESTRICTIONS						
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is there a REMS on this product? 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 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: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier: No Phone: DEA #: NCPDP#: NCPDP#: 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 Code Controlled by State(s)? ARCOS Reportable? Schedule No. No Controlled Substance Code Listed Chemical (List I or II) No If yes, indicate which: Is it a scheduled listed chemical product?: No CLASS OF TRADE RESTRICTION:	RETURN INSTRUCTIONS Contact tel. # if product received damaged: Is product returnable for credit: URL/Link to returns policy:						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	contact - customerservice@camberpharma.com						
Restricted to retail pharmacy only: No	Special regulations or returns requirements for this						
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) No	product in certain states? If so, which states? Other requirements? Comments?						
Comments:							
MISCELLANE	OUS NOTES and/or Image of Product Barcode:						



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FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop S	nip Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI		Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	per:	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 Designa	ed Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order:		Overnight receipt available: PO Receipt cut off time:
Drop Ship miscellaneous fees billed: Comments:		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, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	s and physician offices	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to F	rocess PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:		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?