

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

Version 2021						Introduction Ty	/pe: New Item		x Final	Version			Date:	1/30/	/2024
			PRODUCT INFORMA	TION					SF	PECIAL HAN	IDLING AND STOR	AGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA						a. Temperat	a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 216174							ai rompora	Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)							
Medical Device Class, if applicable:															
DUNS:	11-856-3719								Other Tempera	ture Range I	Requirement	Excursions	ermitted to 1	5° to 30°C (5	i9° to 86°F)
Proprietary Name (If Applicable) a		me: Palipe	ridone Extended-Release Ta						(write in)						
Selling Unit NDC:	31722-319-30		Unit of Use NDC:		31722-319-30		331722319300		Notes						
UDI			CVX Code:			MVX Code:									
Description:	Paliperidone Exter	nded-Release Table	ts 6 mg								d to customers on ic			No	
							Is this product	to be shippe	d to customers on d	ry ice?		No			
Active Ingredient(s): Paliperidone, USP															
URL for Additional Product Inform	nation:	www.camberpharma						b. Contact f	b. Contact for temperature excursion questions:  Name:  Soma Raju						
Address:		Ave (and) 800 Center			1	Address 2:			Number:			732-529-042	3		
City:	Piscataway	tro (ana) ooo oonto	marrivo, cano i		State:	NJ	<b>Zip:</b> 08854		Group E-mail:				eterousa.cor	n	
Key Contact:	Customer Service				Email:	customerservice@	camberpharma.com								
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special re	c. Special regulations for product in any states?					No	
Product Therapeutic Classificatio	n:	Atypical antipsycho	tic						Special returns	requirement	ts for this product?			No	
					_										-
	ADDITIO	ONAL PRODUCT IN	FORMATION			PRODUCT D	ESCRIPTION INFORMATION	d. Store pro	duct (unit of sale	) upright?				No	
The product is?			Is the Product	Direct-Ship (	Only				Protect produ	ct (unit of sa	ale) from light?			No	
a legend device?		No	Is the Product	Unit of Use		Size:	30 ct	e. Shelf life:						24	Months
if yes, enter class #			Orphan Drug Status			0.20.	_		Initial shelf life	at launch (	if different):				Months
a product kit?		No	EDA Assessed Oteston			Strength:	6 mg		ORDER INFORMATION						
if yes, list NDCs of component parts			FDA Approval Status				Film Coated Tablet				OKDEK INFORM	IATION			
reverse numbered?		No				Dosage Form	: Timi Godica Tablet		Unit of Sale			What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						x Bottle	9		1 Bottle of 3			
latex-free?		Yes	Lactose, Dairy, Corn,	Alcohol, Anima	al, Sugar,	Product Shap	Round, cylindrical,		Box/0	Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes	Rennet, Cas	ein, Whey, Dye		r roudet Snap	Diconvex		Ampi						
correctional institution block?		No				Product Color	r: Light beige to beige		Glass			Minimum o	der quantity	?	Yes
opioid?		No	On the of Original	110 4			Printed with "6" in black ink		Tube						
Cannabinoid?  If Unit Dose, is item bar coded to u	init done for	No	Country of Origin	USA		Product Impri	int:			iquid Sgl iquid Multi		If Voc. how	many of whi	ch package	tuno?
hospital scanning?	init dose for		Is this product covered u	inder the						Powder Sql			Each	cii package	typer
If Unit Dose, indicate NDC here:			Trade Agreements Act (		Yes					Power Multi		2-7	Inner/Carton	/Pack	
									Othe	r: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS											
					Aut		*If Authorized Generic, other			PH	IARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB						section fields are not applicab	Rec. sell un	it to customer?			Rx billing u	nit to pharma	асу:	
II. Generic Equivalent to What Bra	nd?:	Invega®											Each		
		DRIIC CURR	LY CHAIN SECURITY ACT	(Dece A) INFO	DMATION			(Write-in, e.	g. 1 Vial)				Gram		
		DRUG SUPPI	LT CHAIN SECURITY ACT	(DSCSA) INFO	RWATION								Milliliter		
Does supplier meet DSCSA defini	tion of manufactur	er?	Yes		GLN:	0331722000000				ITEN	AND PACKING IN	IFORMATIO	١		
Is product exempt from DSCSA?			No												
If ves. select exemption:					GCP:						Dimensi	ons (US msn	nts.)	Volume	Saleable #
Other exemption - Write in:					Ju				W	eight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was or	iginal product purch	hased	Item/Each:		0.09	1.58	1.58	3.5	8.74	1
Is product sold by manufacturer's			Yes		direct from m					0.09	1.56	1.56	3.5	0.74	'
Has FDA granted waiver/exception		oduct?	No		Provide source	e manufacturer for	repackaged product	Box/Carton	/Bundle/						
If yes, attach documentation from	m FDA.							Inner Pack:							
		GT	IN AND HIBCC PRODUCT I	NEORMATION				Case:		2.55	10.25	7	4.5	322.88	24
		GI	IN AND HIDCO PRODUCT I	NI OKMATION				Pallet:							
Saleable Unit of Measure	S	aleable Quantity	HIBCC		GTI	N-14	Unit of Use GTIN-14								
X Item/Each	J	1				31722319300	00331722319300								
Box/Carton/Bundle/Inner Pack									COST INF	ORMATION			WHOLESAL	ER USE ONL	_Y:
X Case		24			1033	31722319307							·		
Pallet								Regular Co				Vendor #:			
	_							Invoice Cos	t (WAC) (\$)		\$65.00	Whsl. Code			
	-							As of date:	1/16/	2024		Fineline Co	JC.		
								713 of date.	17.107			i			
			Attach copy of SAFETY D	ATA SHEET (SI	OS) or non hazar	rd letter, PACKAGE I	NSERT, LABEL AND PHOTO	OF PRODUCT PACE	KAGING and BAR	CODE.		<u> </u>			



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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?  b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	SDS Hazard Classification					
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 e. Inhalation Hazard?	Hazardous Waste Identification  EPA Hazardous Waste Code:  Waste Characteristics					
Is this product regulated for shipment by IATA?	LEATIAZATUOUS WASTE COUE.					
(if yes, answer a-e below and provide SDS)	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?  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#	Registry:  Registry Program Contact Name:  Phone:					
ADD'L STORAGE INFORMATION	Comments					
Is the Product  Controlled Substance?  Controlled Substance Code  Controlled by State(s)?  No  Listed Chemical (List I or II)  No	RETURN INSTRUCTIONS					
ARCOS Reportable?  Schedule No.  If yes, indicate which:  Is it a scheduled listed chemical product?:  No	Contact tel. # if product received damaged:  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  Restricted to retail pharmacy only:  No	contact - customerservice@camberpharma.com					
Restricted to retail pharmacy only:  Restricted to hospital, clinics, and physician offices only:  Restricted from US territories? (explain in comments)  No	Special regulations or returns requirements for this product in certain states?  If so, which states? Other requirements? Comments?					
Comments:	The state of the s					
MISCELLA	NEOUS 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 Ship Product	Standard Order Receipt and Processing					
Purchase orders may be accepted by:		Purchase order daily receipt cut off time by supplier					
a. EDI		Cut off time:					
b. Autofax	Fax Number:						
c. Fax	Fax Number:	Shipping lead time of PO: Hours	Days				
d. Phone only	Phone No.:						
e. Supplier Web Site only	Site Address:	Ships same day for next day receipt:					
Minimum Order Quantity:		Ships for second day receipt:					
Supplier's Customer Service Number:		Ships regular ground for 3-10 days receipt:					
Contracted 3PL company / contact #:	Name:						
	Phone:						
Expedited Freight Cha	rges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Pro	cessing				
Expedited freight fees billed with each orde	er:	Overnight receipt available:					
Drop Ship service fee billed with each orde	r:	PO Receipt cut off time:					
Drop Ship miscellaneous fees billed:		Days of week overnight is available:	Monday				
Comments:		,	Tuesday				
			Wednesday				
			Thursday				
			Friday				
		Priority Overnight receipt available:					
Cla	ss of Trade Restriction:	PO Receipt Cut off time:					
No restriction: Select VES if sold to retail of	narmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:					
Restricted to retail pharmacy only:	larmacy, nospitals, clinics and physician offices	PO Receipt Cut off time:					
Restricted to hospital, clinics, and physician	o offices only:	Phone: Phone #					
Restricted from US territories? (explain in c		Order receipt method: Fax: Fax #:					
Comments:		EDI:					
		Overnight Fees apply:					
		Other fees apply:					
Other Data Inf	ormation Required to Process PO:	Return Instructions					
Patient Procedure Date:		Contact # if product is received damaged:					
Physician Name:		Is product returnable for credit:					
Physician/Clinic Phone #		URL/Link to returns policy:					
Physician State License #							
Physician/Clinic DEA #:		Special regulations or returns requirements for this product in certa	ain states?				
Physician/Clinic Specialty:		If so, which states? Other requirements? Comments?					
	Miscellaneous Notes:						
		ADDITIONAL INFORMATION					
		Is product order for scheduled patient procedure?					
		Is product order for restocking purposes?					
		13 product order for restocking purposes:					