

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

Version 2024						Introduction Type	: New Item	x	Final Version			Date:	7/30	/2024
			PRODUCT INFORMAT	TION					SPECIAL HAN	IDLING AND STOR.	AGE REQUIP	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA							a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/AN	IDA/BLA; PMA/510	O(k): 216174				NDA 505(b) Type:	NOT APPLICABLE	Temper	rature Range	Controlled Room -	between 20	and 25 C (68	° – 77° F)	
Medical Device Class, if applica														
DUNS:	11-856-3719							Other T	emperature Range	Requirement	Excursions p	ermitted to 1	5° to 30°C (5	9° to 86°F)
Proprietary Name (If Applicable) a		ame: Paliperi	idone Extended-Release Tal	blets 3 mg					vrite in)					
Selling Unit NDC:	31722-318-30		Unit of Use NDC:		31722-318-30		1722318303	Notes						
UDI			CVX Code:			MVX Code:								
Description:	Paliperidone Exte	ended-Release Tablets	3 mg						product to be shippe				No	
								Is this p	product to be shipped	d to customers on d	ry ice?		No	
Active Ingredient(s):		Paliperidone, USP						b. Contact for temper	atura avauraian au	actions				
URL for Additional Product Inform	mation:	www.camberpharma	.com					Name:	ature excursion qu		Soma Raju			
Address:	800 Centennial A					Address 2:		Numbe	r:		732-529-042	3		
City:	Piscataway				State:	NJ Z	ip: 08854	Group			somaraju@h	eterousa.cor	<u>n</u>	
Key Contact:	Customer Service	е	Email: customerservice@camberpharma.com											
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special regulations					No	
Product Therapeutic Classification	on:	Atypical antipsychoti	ic					Special	returns requiremen	ts for this product?			No	
	ADDIT	IONAL PRODUCT INF				PRODUCT DES	CRIPTION INFORMATION	d. Store product (unit					No	
The product is?			Is the Product	Direct-Ship C	Only				product (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 #		Nie	Orphan Drug Status				2 777 77	Initial s	shelf life at launch (if different):				Months
a product kit? if yes, list NDCs of		No	FDA Approval Status			Strength:	3 mg			ORDER INFORM	ATION			
component parts			T DA Approvar Status				Film coated tablet			ONDER HIT ON	,,,,,			
reverse numbered?		No				Dosage Form:		Unit of	Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present					x	Bottle		1 Bottle of 3			
latex-free?		Yes	Lactose, Dairy, Corn, A			Product Shape:	Round, cylindrical,		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes	Rennet, Case	in, Whey, Dye		. roundt onapor	biconvex		Ampule					
correctional institution block?		No				Product Color:	Light pink to pink		Glass		Minimum or	der quantity	?	Yes
opioid? Cannabinoid?		No No	Country of Origin	USA			Printed with '3' in black ink		Tube Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for	140	Country of Origin	00/1		Product Imprint:	Timed with 5 in black link		Vial Liquid Sgr		If Yes, how	many of whi	ch nackage	tyne?
hospital scanning?	unit 0000 101		Is this product covered ur	nder the					Vial Powder Sql			Each	on paonago	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
If Unit Dose, indicate NDC here:			Trade Agreements Act (T	AA)?	Yes				Vial Powder Multi			Inner/Carton	/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PRO	DDUCTS										
				_	Au		Authorized Generic, other			IARMACY ORDER				
I. Orange Book Rating:	AB					se	ction fields are not applicable	Rec. sell unit to custo	mer?		Rx billing u		асу:	
II. Generic Equivalent to What Bra	and?:	Invega						OM-Stalland ANS-D				Each		
		DRUG SUPPLY	Y CHAIN SECURITY ACT (I	DSCSA) INFO	RMATION			(Write-in, e.g. 1 Vial) HCPCS J-Code:				Gram Milliliter		
		5.100 00.112		30007., 0.				nor oo o oodc.				Williame		
Does supplier meet DSCSA defini	ition of manufactu	irer?	Yes	Т	GLN:	0331722498975			ITEN	AND PACKING IN	IFORMATION	١		
Is product exempt from DSCSA?			No											
If yes, select exemption:					GCP:					Dimensio	ons (US msm	its.)	Volume	Saleable #
Other exemption - Write in:									Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			riginal product purchas	sed	Item/Each:	0.08	1.55	1.55	3.15	7.57	1
Is product sold by manufacturer's			Yes No	4	direct from n									·
Has FDA granted waiver/exceptio		roduct?	NO		Provide sour	ce manufacturer for re	packaged product	Box/Carton/Bundle/						
If yes, attach documentation fro	III FDA.							Inner Pack: Case:						
		GTIN	AND HIBCC PRODUCT IN	IFORMATION				Case.	2.3	10	6.75	3.75	253.13	24
								Pallet:						
Saleable Unit of Measure	RFID tag(Y/N)	Saleable	HIBCC		GTI	IN-14	Unit of Use GTIN-14							
		Quantity												
x Item/Each	N	1			003	331722318303	00331722318303	0.00	ST INFORMATION			AULOL EGAL	ER USE ONL	V
Box/Carton/Bundle/Inner Pack X Case	N	24			100	331722318300		CO	ST-INFORMATION			WHOLESAL	ER USE UNL	.1.
X Case	IN	24			103	001122010000		Regular Cost			Vendor #:			
, and								Invoice Cost (WAC) (\$	5)	\$65.00	Whsl. Code	#:		
									-	722.00	Fineline Co			
								As of date:	1/23/2024]			
1								<u> </u>						
*PI			Attach copy of SAFETY DA	TA SHEET (SI	OS) or non haza		SERT, LABEL AND PHOTO OF F							
*Please provide any additional inf	tormation on page	2.				See new p. 3 for Des	signated Drop Ship Only.	Signati	ıre:					



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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?	SDS Hazard Classification						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	J. J						
Is the product a CA Prop 65 carcinogen?	x Organic Corrosive						
Is the product a CA Prop 65 carcinogen? No							
Does the product label bear a CA Prop 65 warning?							
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact nazard						
c. Contact Hazard?	Does the product have an Aerosol class? If yes, No						
d. Does this product require special clean-up instructions?							
(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? Yes						
(if yes, answer a-e below and provide SDS)	If yes, indicate which: Group 2 items (non-antineoplastic that meets a hazard criterion)						
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						
<u></u>							
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							
b. Proper Shipping Name	Is there a REMS on this product?						
c. DOT Hazard Class	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 No						
Passenger	Limited Distribution Requirement						
Cargo	Comments / Details: (For example, iPledge program?)						
	Confinents / Details. (For example, Preuge program?)						
Passenger & Cargo							
Is this a reportable quantity? No	REMS: No						
RQ Threshold:	REMS Program Manager Name: Phone:						
Is this a marine pollutant? No	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);							
SP#	Registry: No						
	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: 1-866-827-3647						
Schedule No. Is it a scheduled listed chemical product?: No	ls product returnable for credit:						
CLASS OF TRADE RESTRICTION:	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:	Special regulations or returns requirements for this						
Restricted to hospital, clinics, and physician offices only: No							
Restricted to hospital, clinics, and physician offices only. Restricted from US territories? (explain in comments) No	140						
	ii so, windi states: Other requirements? Comments?						
Comments:							
MISCELLA	ANEOUS NOTES and/or Image of Product Barcode:						
- WIGGLEEP							



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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:	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: 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: Saturday Overnight receipt available: PO Receipt Cut off time: Phone: 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?						