

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

Version 2024						Introduction 7	Type: New Item		x Final Version			Date:	4/7/	2025	
			PRODUCT INFORMA	TION					SPECIAL HAN	IDLING AND STOR	RAGE REQUI	REMENTS*			
Company Name: Camber Pharmaceuticals, Inc.						Applica	tion: ANDA	a. Temperatu	a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/AN	DA/BLA; PMA/510)(k): 2	18272			NDA 505(b) Type	NOT APPLICABLE		Temperature Range	Controlled Room		and 25 C (68	s° – 77° F)		
Medical Device Class, if applical	ble:														
DUNS:	11-856-3719								Other Temperature Range	Requirement	Excursions	permitted to 1	5° to 30°C (5	i9° to 86°F)	
Proprietary Name (If Applicable) a		ame:	Chlorpromazine Hydrochloride Inje	ction, USP 50 r	mg/2 mL (25 mg				(write in)						
Selling Unit NDC:	31722-367-32		Unit of Use NDC:			UPC: MVX Code:	331722367325		Notes						
UDI			CVX Code:			MVX Code:									
Description:	Chlorpromazine H	Hydrochloride In	ection, USP 50 mg/2 mL (25 mg/r	nL) Single-Dose	e Vials				Is this product to be shippe				No	-	
Active Ingredient(s): Chlorpromazine hydrochloride, USP									Is this product to be shipped to customers on dry ice? No b. Contact for temperature excursion questions:						
URL for Additional Product Information: www.camberpharma.com								b. Contact to	r temperature excursion qu Name:	estions:	Soma Raju				
Address:	800 Centennial A		nama.com		T	Address 2:			Number:		732-529-042	23			
City:	Piscataway				State:	NJ	Zip: 08854		Group E-mail: somaraju@heterous				<u>n</u>		
Key Contact:	Customer Service	9			Email:		@camberpharma.com								
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special re	c. Special regulations for product in any states?						
Product Therapeutic Classification	n:	Antipsychotic	drug						Special returns requirement	ts for this product?			No		
														1	
	ADDITI	IONAL PRODUC	CT INFORMATION			PRODUCT	DESCRIPTION INFORMATION	d. Store prod	luct (unit of sale) upright?				No		
The product is?			Is the Product	Direct-Ship C	Only			_	Protect product (unit of sa	ale) from light?			No		
a legend device? if yes, enter class #		No	Is the Product Orphan Drug Status	Unit Dose		Size:	25 x 2 mL single-dose vials	e. Shelf life:	Initial shelf life at launch (if different).			24	Months Months	
a product kit?		No	Orphan Drug Status				50 mg/2 mL (25 mg/mL)		initial shell life at launch (ir differenty:				Wonths	
if yes, list NDCs of		110	FDA Approval Status			Strength:	per single-dose vial			ORDER INFOR	MATION				
component parts						Dosage Fori	Sterile, clear solution								
reverse numbered?		No				Dosage i oii			Unit of Sale			NDC selling			
co-licensed?		No	Allergens Present				NVA		Bottle			25 x 2 mL Sin		als	
latex-free? preservative-free?		Yes				Product Sha	npe: N/A		x Box/Carton Ampule		(Write-in, e	.g. 1 Box of 1	0 Vials)		
correctional institution block?		No					Colorless		x Glass		Minimum o	rder quantity	17	Yes	
opioid?		No				Product Col	or:		Tube			· uo: quuinity	•	100	
Cannabinoid?		No	Country of Origin	India		Product Imp	N/A		x Vial Liquid Sgl						
If Unit Dose, is item bar coded to u	ınit dose for					r roduct imp	ant.		Vial Liquid Multi		If Yes, how	many of whi	ch package	type?	
hospital scanning?		Yes	Is this product covered u						Vial Powder Sgl		1	Each			
If Unit Dose, indicate NDC here:		31722-367-31	Trade Agreements Act (1	AA)?	No				Vial Powder Multi Other: Write In			Inner/Carton Case	/Pack		
			FOR GENERIC DRUG PR	ODUCTS					Other. Write in			Case			
			FOR GENERIC DRUG FR	ODUCIS											
					Au	uthorized Generic	*If Authorized Generic, other		Pŀ	ARMACY ORDER	R / BILL UNIT				
I. Orange Book Rating:	AP						section fields are not applicable	Rec. sell unit	Rec. sell unit to customer? Rx billing unit to pharmacy:						
II. Generic Equivalent to What Brand?: Chlorpromazine Hydrochloride Injection, USP RLD of Hikma Pharmaceuticals					USA Inc.		Each								
·							(Write-in, e.g. 1 Vial)								
		DRUG S	UPPLY CHAIN SECURITY ACT (DSCSA) INFO	RMATION			HCPCS J-Co				Milliliter			
Does supplier meet DSCSA defini	tion of manufactu	ror2	Yes	_	GLN:	0331722498975			J3230	AND PACKING I	NEOPMATIO	N			
Is product exempt from DSCSA?	tion of manufactu	reir	No	-	GLN.	0331722496973			11 = 11	I AND I ACKING I	INI OKWATIO	IN .			
If yes, select exemption:			·		GCP:					Dimena	ions (US msr	nte)	Volume	Saleable #	
Other exemption - Write in:					JUI.				Weight Lbs.	Depth	Width	Height	(Cube)	Pieces	
Is product repackaged?			No		If yes, was o	riginal product pur	chased	Item/Each:	0.49	3.38	3.38	2.25	25.70	1	
Is product sold by manufacturer's			Yes		direct from n	nfr?				3.36	3.30	2.25	25.70		
Has FDA granted waiver/exception		roduct?	No		Provide sour	ce manufacturer fo	or repackaged product	Box/Carton/E	Bundle/						
If yes, attach documentation from	m FDA.							Inner Pack:							
			GTIN AND HIBCC PRODUCT II	NEORMATION				Case:	9.7	11	11	5.5	665.5	18	
			517525515551					Pallet:							
Saleable Unit of Measure	RFID tag(Y/N)	Saleable	HIBCC		GT	IN-14	Unit of Use GTIN-14								
		Quantity			_			[]							
x Item/Each	N	1			003	331722367325			COST INFORMATION			WHOLESAL	ED LICE OW	V	
Box/Carton/Bundle/Inner Pack	N	18			203	31722367329			COST INFORMATION			WHOLESALI	ER USE ONL	т:	
X Case Pallet	IN	10			203	31122301329		Regular Cos	•		Vendor #:				
1 direk								Invoice Cost		\$715.00	Whsl. Code	#:			
											Fineline Co				
								As of date:	4/1/2025						
 			August CAFETY DA	TA CLIEFT (OF)C) as see b	and letter DACKAGE	INSERT, LABEL AND PHOTO	OF DECEMBER 124 OF	ACING and DARCODE						
*Please provide any additional inf	ormation on nace	2	Allach copy of SAFETY DA	IIA SHEET (SL	ט נפע non naza		: INSERT, LABEL AND PHOTO	OF FRUDUCI PACK	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? 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?	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					
ls this product regulated for shipment by IATA?	EFA Hazaiuous waste Code.					
(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); SP#	Comments Registry: No					
	Registry Program Contact Name: Phone:					
ADD'L STORAGE INFORMATION	Comments					
Is the Product Controlled Substance? 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	RETURN INSTRUCTIONS 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 Yes	contact - customerservice@camberpharma.com					
Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: No 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:						
MISCELLAN	EOUS 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: a. EDI b. Autofax Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time:						
c. Fax d. Phone only Phone No.:	Shipping lead time of PO: Hours Days						
e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	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:	Overnight receipt available:						
Drop Ship service fee billed with each order:	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, 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/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?						