

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

Version 2024						Introduction Type:	: New Item	x	Final Version			Date:	1/28	/2025
			PRODUCT INFORMAT	TION					SPECIAL HAN	IDLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	Camber Pharma	ceuticals, Inc.				Application:	ANDA	a. Temperature - Indi	cate the USP tempe	erature range for th	nis product.			
Application Number for NDA/AN						NDA 505(b) Type:	NOT APPLICABLE		rature Range	Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applical	ble:								-					
DUNS:	11-856-3719							Other 1	emperature Range I	Requirement	Excursions p	ermitted to 1	5° to 30°C (5	9° to 86°F)
Proprietary Name (If Applicable) a		ame: Potassi	ium Chloride Extended-Rele	ase Tablets, US	P 10 mEq				vrite in)					
Selling Unit NDC:	31722-133-01		Unit of Use NDC:				722133012	Notes						
UDI			CVX Code:			MVX Code:								
Description:	Potassium Chlori	ide Extended-Release	Tablets, USP 10 mEq						product to be shipped				No	
Active Ingredient(s): Potassium chloride, USP									product to be shipped	d to customers on d	ry ice?		No	
								b. Contact for temper	ature excursion qu					
URL for Additional Product Inforn		www.camberpharma	.com					Name:			Soma Raju			
Address:	800 Centennial A Piscataway	Ave, Suite 1			State:	Address 2:	00054	Numbe			732-529-042			
City: Key Contact:	Customer Service	Δ			Email:	customerservice@car	p: 08854	Group	E-mail:		somaraju@h	eterousa.cor	<u>n</u>	
Phone Number:	1-866-827-3647	С			Fax:	732-562-8788	niberpriarma.com	c. Special regulations	for product in any	states?			No	1
Product Therapeutic Classificatio		Electrolyte replenish	er			1.12.112							No	
Product Therapeutic Classification:    Special returns requirements for this product?   No														
	ADDIT	IONAL PRODUCT INF	ORMATION			PRODUCT DESC	CRIPTION INFORMATION	d. Store product (unit	of sale) upright?				No	1
The product is?			Is the Product	Direct-Ship O	nly			Protec	t product (unit of sa	ale) from light?			No	ĺ
a legend device?		No	Is the Product	Neither		Size:	100 ct	e. Shelf life:	, ,	, ,			24	Months
if yes, enter class #			Orphan Drug Status			SIZE.		Initial	shelf life at launch (	if different):				Months
a product kit?		No				Strength:	10 mEq K (750 mg)							
if yes, list NDCs of			FDA Approval Status				Extended-release tablet of			ORDER INFORM	ATION			
component parts reverse numbered?		No				Dosage Form:	microencapsulated crystals	Unit of	Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present					X X			1 Bottle of 10			
latex-free?		Yes		ohol		Product Shape:	Modified capsule,		Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		Yes	Aic	onioi		Froduct Snape.	biconvex		Ampule					
correctional institution block?		No				Product Color:	White		Glass		Minimum or	der quantity	?	Yes
opioid? Cannabinoid?		No	Country of Origin	USA			Debossed with 'A10' on one side and		Tube					
If Unit Dose, is item bar coded to u	init dose for	No	Country of Origin	USA		Product Imprint:	plain on the other side		Vial Liquid Sgl Vial Liquid Multi		If Yes, how	many of whi	ch nackane	tvne?
hospital scanning?	ariit dosc ioi		Is this product covered up	nder the					Vial Powder Sql			Each	on package	турс.
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										
									DI	IARMACY ORDER	/ DILL LINET			
				_	AL		Authorized Generic, other tion fields are not applicable							
I. Orange Book Rating:	AB1	Detection Objects	(141)			360	ation fields are not applicable	Rec. sell unit to custo	omer?		Rx billing ur		acy:	
II. Generic Equivalent to What Bra	ina ::	Potassium Chloride	(Merck)					(Write-in, e.g. 1 Vial)				Each Gram		
		DRUG SUPPLY	Y CHAIN SECURITY ACT (I	DSCSA) INFOR	MATION			HCPCS J-Code:				Milliliter		
			,	,										
Does supplier meet DSCSA defini	ition of manufactu	irer?	Yes		GLN:	0331722498975			ITEN	AND PACKING IN	IFORMATION	١		
Is product exempt from DSCSA?			No											
If yes, select exemption:					GCP:				Weight Lbs.	Dimensio	ons (US msm	ıts.)	Volume	Saleable #
Other exemption - Write in:									Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No Yes		If yes, was or direct from n	riginal product purchas	ed	Item/Each:	0.29	2.2	2.2	4.1	19.84	1
Is product sold by manufacturer's Has FDA granted waiver/exceptio			No	→		ce manufacturer for rep	nackaged product	Box/Carton/Bundle/						
If yes, attach documentation from		oudet:	110		r rovide sour	ce manufacturer for rep	Jackageu product	Inner Pack:						
, , , , , , , , , , , , , , , , , , , ,								Case:	7.5	14.2	10.25	4.75	691.36	24
		GTIN	I AND HIBCC PRODUCT IN	IFORMATION					7.5	14.2	10.25	4.75	091.30	24
								Pallet:						
Saleable Unit of Measure	RFID tag(Y/N)		HIBCC		GTI	IN-14	Unit of Use GTIN-14							
X Item/Each	N	Quantity 1			003	331722133012								
Box/Carton/Bundle/Inner Pack	- 14					01122100012		CO	ST INFORMATION		1	WHOLESAL	ER USE ONL	.Y:
X Case	N	24			103	331722133019								
Pallet								Regular Cost			Vendor #:			
								Invoice Cost (WAC) (	5)	\$33.88	Whsl. Code			
								As of date:	3/1/2021		Fineline Cod	de:		
								AS OF GARE:	3/ 1/2021		1			
			Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza	ard letter, PACKAGE INS	ERT, LABEL AND PHOTO OF F	PRODUCT PACKAGING a	nd BARCODE.					
*Please provide any additional inf	ormation on page		• •	<b>,</b>			ignated Drop Ship Only.	Signat						



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

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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HA	ZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply):							
a. Cytotoxic?	SDS Hazard Classification						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?							
Is the product a CA Prop 65 carcinogen?	Organic Corrosive						
Is the product a CA Prop 65 reproductive toxicant?	x Inorganic Oxidizer						
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard						
c. Contact Hazard?	Does the product have an Aerosol class? If yes, No						
d. Does this product require special clean-up instructions?	identify NFPA Storage Level:						
(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?						
(if yes, answer a-e below and provide SDS)	If yes, indicate which:						
a. UN/Identification Number	n yes, maleate which.						
b. Proper Shipping Name							
c. DOT Hazard Class	Hazardous Waste Identification						
d. Packing Group							
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics						
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	REMOUT REGISTRY RESTRICTIONS						
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?	1100010 0112						
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?)						
Passenger & Cargo	Comments / Details. (For example, if leage programs)						
	25112						
Is this a reportable quantity? No	REMS: No						
RQ Threshold:  Is this a marine pollutant?  No	REMS Program Manager Name:  Phone:  Phone:						
Is this a marine pollutant? No Is this product shipped utilizing an authorized DOT exception or Special Permit?	Supplier Manages REMS registry exclusively:  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)	by Supplier.						
Special Permit; DOT-SP	Comments						
Special Provision (listed in Column 7 of 49 CFR 172.101);	- Simulation						
SP#	Registry: No						
<u> </u>	Registry Program Contact Name: Phone:						
ADD'L STORAGE INFORMATION	Registry Program Contact Name.  Comments						
	Odifficia						
Is the Product	RETURN INSTRUCTIONS						
Controlled Substance?  No Controlled Substance Code	RETURN INSTRUCTIONS						
Controlled by State(s)?  ARCOS Reportable?  No  Listed Chemical (List I or II)  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							
	Is 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	product in certain states?						
Restricted to hospital, clinics, and physician onices only.  Restricted from US territories? (explain in comments)  No	If so, which states? Other requirements? Comments?						
Comments:	The state of the s						
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 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?						