

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

Version 2024					Introduction Type:	New Item	x	Final Version			Date:	2/23/	/2025
		PRODUCT INFORM	TION					SPECIAL HAN	DLING AND STOP	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. ANDA							a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/AN	IDA/BLA; PMA/510(k):	214422			NDA 505(b) Type:	NOT APPLICABLE		erature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applical	ble:												
DUNS:	11-856-3719						Other	Temperature Range F	Requirement	Excursions p	permitted to 1	5° to 30°C (5	i9° to 86°F)
Proprietary Name (If Applicable) a		Potassium Chloride Extended-Re) mEq				(write in)					
Selling Unit NDC: UDI	31722-133-05	Unit of Use NDC CVX Code:			UPC: 331 MVX Code:	722133050	Notes						
					WIVA Code.					-			1
Description:	Potassium Chloride Extende	ed-Release Tablets, USP 10 mEq						product to be shipped				No	-
Active Ingredient(s):	Potassiu	ım chloride, USP						product to be shipped	a to customers on o	iry ice?		No	
Active ingredient(s).	1 0123310						b. Contact for tempe	rature excursion qu	estions:				
URL for Additional Product Inform	mation: www.car	nberpharma.com					Name			Soma Raju			
Address:	800 Centennial Ave, Suite 1				Address 2:		Numb	er:		732-529-042	23		
City:	Piscataway			State:		08854	Grou	o E-mail:		somaraju@h	eterousa.cor	<u>n</u>	
Key Contact:	Customer Service			Email:	customerservice@carr	berpharma.com							1
Phone Number:	1-866-827-3647	de anales la bas		Fax:	732-562-8788		c. Special regulation					No	-
Product Therapeutic Classificatio	Electroly	te replenisher					Speci	al returns requirement	is for this product?			No	
	ADDITIONAL PR	ODUCT INFORMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store product (un	it of sale) upright?				No	1
The product is?	ABBIHONAL PR	Is the Product	Direct-Ship Only		I RODOOT DESC				ale) from light?			No	1
a legend device?	No	Is the Product	Neither			500 ct	e. Shelf life:	ct product (unit of sa	ale) from light?			24	Months
if yes, enter class #	140	Orphan Drug Status			Size:	500 01		shelf life at launch (if different):			27	Months
a product kit?	No				Chronith	10 mEq K (750 mg)							
if yes, list NDCs of		FDA Approval Status			Strength:				ORDER INFORM	IATION			
component parts					Dosage Form:	Extended-release tablet of microencapsulated crystals							
reverse numbered?	No	Allermone Dresent			•	microencapsulated crystals	Unit o			What is the		unit?	
co-licensed? latex-free?	No Yes	Allergens Present				Modified capsule,	X	Bottle Box/Carton		1 Bottle of 5	g. 1 Box of 1	0 \/iale)	
preservative-free?	Yes	AI	cohol		Product Shape:	biconvex		Ampule		(11111111111111111111111111111111111111	g. I Dox of h	5 viais)	
correctional institution block?					Breduct Colory	White		Glass		Minimum or	der quantity	?	Yes
opioid?	No				Product Color:			Tube					
Cannabinoid?	No	Country of Origin	USA		Product Imprint:	Debossed with 'A10' on one side and plain on the other side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for							Vial Liquid Multi		If Yes, how		ch package	type?
hospital scanning? If Unit Dose, indicate NDC here:		Is this product covered Trade Agreements Act						Vial Powder Sgl Vial Powder Multi			Each Inner/Carton	/Book	
Il Onit Dose, indicate NDC nere:		Trade Agreements Act	TAA): Tes	·				Other: Write In			Case	Pack	
		FOR GENERIC DRUG P	ODUCTS							1	louoo		
				Aut		uthorized Generic, other		PH	IARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB1				sect	ion fields are not applicable	Rec. sell unit to cus	tomer?		Rx billing u	nit to pharma	acy:	
II. Generic Equivalent to What Bra	and?: Potassiu	m Chloride (Merck)									Each		
	DD						(Write-in, e.g. 1 Vial)				Gram		
	DR	UG SUPPLY CHAIN SECURITY ACT	(DSCSA) INFORMAT	IUN			HCPCS J-Code:		1		Milliliter		
Does supplier meet DSCSA defini	ition of manufacturer?	Yes	GLN	N:	0331722498975			ITEN	AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?		No											
If yes, select exemption:			GCF	P:			1		Dimensi	ons (US msn	nts.)	Volume	Saleable #
Other exemption - Write in:							1	Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?		No			iginal product purchase	ed	Item/Each:	1.25	3.17	3.17	6.25	62.81	1
Is product sold by manufacturer's		Yes		ect from m									
Has FDA granted waiver/exception If yes, attach documentation from		NO	Prov	vide sourc	ce manufacturer for rep	ackaged product	Box/Carton/Bundle/ Inner Pack:						
in yes, attach documentation froi							Case:				_		
		GTIN AND HIBCC PRODUCT	NFORMATION					15.7	14.25	10.75	7.25	1110.61	12
							Pallet:						
Saleable Unit of Measure	RFID tag(Y/N) Saleable			GTI	N-14	Unit of Use GTIN-14							
here (Feel	Quantity			0000	21722122050								
x Item/Each	N 1			0033	31722133050		C					ER LISE ONI	v.
Box/Carton/Bundle/Inner Pack	N 12			103	31722133057						ALI OLLOALI		
X Case							Regular Cost			Vendor #:			
X Case Pallet								(\$)	£4.00.40	MIL			
							Invoice Cost (WAC)	(Ψ)	\$169.40	Whsl. Code	#:		
									\$169.40	Fineline Co			
							As of date:	3/1/2021	\$169.40				
									\$169.40				
		Attach corr of SAETTY D					As of date:	3/1/2021	\$109.40				
		Attach copy of SAFETY D	ATA SHEET (SDS) or	r non hazar		ERT, LABEL AND PHOTO OF F gnated Drop Ship Only.	As of date:	3/1/2021 and BARCODE.	\$169.40				

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Version 2024 For Desig	nated 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? Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? No	SDS Hazard Classification Organic Corrosive x Inorganic 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? Is this product regulated for shipment by DOT? No	Does the product have an Aerosol class? If yes, No identify NFPA Storage Level: NFPA Storage Level:					
(if yes, answer a-e below and provide SDS) a. UN/dentification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	If yes, indicate which: Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics					
Is this product regulated for shipment by IATA? No (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? No If Yes, is it managed with a pharmacy registry? Website URL:					
Is the product restricted for air shipment? If so, indicate restriction: No 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: No REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: Phone: Wholesale distributor support: DEA #: Provider Name: DEA #: Site Enrollment Number assigned NCPDP#: by Supplier: 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 V					
Is the Product Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No	RETURN INSTRUCTIONS					
ARCOS Reportable? No If yes, indicate which: Schedule No. If yes, indicate which: Is it a scheduled listed chemical product?: No CLASS OF TRADE RESTRICTION:	Contact tel. # if product received damaged: 1-866-827-3647 Is product returnable for credit: Yes 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 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? No If so, which states? Other requirements? Comments?					
Comments:						
MISCELLA	NEOUS NOTES and/or Image of Product Barcode:					



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Version 2024 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: c. Fax Fax Number: d. Phone only Phone No.: e. Supplier Web Site only Site Address: Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name:	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:
Phone:	Overnight and Drivity Overnight DO Broossing
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: PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: PO Receipt Cut off time: Phone: Order receipt method: Phone: Fax: EDI: EDI: Covernight Fees apply: Other fees apply: Image: Covernight Fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	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?