

## **Standard Pharmaceutical Product Information (Rx Product Only)**

© August 2014						Introdu	uction Type:	:	New Item		Final Version			Date:		
			PRODUCT INFORI								SPECIAL HANDL	ING AND ST	DRAGE REQ	UIREMENTS	5*	
Company Name:	Camber Pharmaceut	icals					Applicati	ion:	ANDA	a. Temperature – In	licate the USP temper	rature range f	or this produ	ıct.		
Application Number for ND	DA/ANDA/BLA (drug);	PMA/510(k)(med d	levice):	21	14422						erature Range				een 20 and 25	5 C (68° – 77° I
DUNS:	826774775				1					Other	Temperature Range Re	equirement				
Proprietary Name (If Applica		Name: Po	tassium Chloride Extended Re		(750 mg) 10 mEq						(write in)					
Selling Unit NDC:	31722-133-01		Individual Unit ND	C:				72213301	2							
UDI			CVX Code:			MVX C	ode:				product to be shipped				No	-
Description: White modified capsules shaped biconvex tablets debossed with "A10" on one side and plain on other.						Is this	Is this product to be shipped to customers on dry ice? No									
Active Ingredient(s):		Potassium Chlorid	le							b. Contact for tempe Name	rature excursion ques	stions:	Soma Raiu			
URL for Additional Product	Information:	www.camberpharm	na.com							Numb			732-529-042	23		
Address:	1031 Centennial Ave					Address 2	:			Grou	E-mail:		somaraju@l	neterousa.co	m	
City:	Piscataway			State: NJ Zip: 08854												
Key Contact:	Customer Service			Email: customerservice@camberpharma.com				is for product in any s				No	-			
Phone Number:		732-529-0430			Fax: 732-562-8788			Special returns requirements for this product? No								
Product Therapeutic Classif	fication:				1					d. Store product (un	it of colo) upright?				No	
ADDITIONA	AL PRODUCT INFORM				PF		ESCRIPTION	N INFORM	ATION		ct product (unit of sale	e) from light?	,		No	-
Is the Product										e. Shelf life:		-, <b>.</b>			24	Months
a legend device?		No	5								shelf life at launch (if	different):			24	Months
reverse numbered?		No			Size:	10	0				enen nie at idanen (i	unioroni,				montaio
co-licensed?		No			Strength:	(7)	50 mg) 10 m	Fak			C	ORDER INFO	RMATION			
Is the Product		Direct-Ship Only			Su engui.	(7,	50 mg) 10 m									
Is the Product		Neither			Dosage Form:	Sc	olid Oral - Ext	tended Re	lease Tablet		f Sale		What is the		y unit?	
										<u>x</u>	Bottle Box/Carton		1 bottle of 1	g. 1 Box of 1	() Viale)	
If Unit Dose, is item bar code	led to unit dose for hos	pital scanning? No	)		Desident Ober		Le se se				Ampule		(11110-111, 0	g. 1 Dox of 1	10 11013)	
If Unit Dose NDC, indicate N	NDC here:				Product Shape	e: 01	olong				Glass		Minimum o	rder quantit	y?	Yes
		110.4			Product Color:	w	hite				Tube					
Country of Origin		USA									Vial Liquid Sgl Vial Liquid Multi		If Yes how	many of wh	ich package	type?
Is this product covered unde	er the Trade Agreemen	ts Act (TAA)?			Product Imprir	nt: "A	10" on one s	side and pla	ain on other		Vial Powder Sql			Each	icii package	type:
											Vial Power Multi			Inner/Cartor	/Pack	
											Other: Write In	_		Case		
			FOR GENERIC DRUG	PRODUCTS												
					Autho	rized Gener	ic *lfA	Authorized	Generic, other section		PHAR	RMACY ORDE	R / BILL UN	Т		
I. Orange Book Rating: AB1					fields are not applicable				Rec. sell unit to customer?			Rx billing unit to pharmacy:				
II. Generic Equivalent to What Brand?: Klor-Con M 10											Each					
				T (D0004) INF						(Write-in, e.g. 1 Vial)				Gram		
		DRUG SI	UPPLY CHAIN SECURITY AC	T (DSCSA) INF	ORMATION									Milliliter		
Does supplier meet DSCSA		cturer?	Yes	G	LN:	033172200	00000			ITEM AND PACKING INFORMATION						
Is product exempt from DSC	CSA?		No	_												
If yes, select exemption: Other exemption - Write in:											Weight Lbs.	Dimer Depth	nsions (US m Height	ismts.) Width	Volume (Cube)	# Pieces:
Other exemption - Write in: Is product repackaged?			No	lf	Yes, was origina	al product n	ourchased d	lirect		Item:		Deptn	-		(oune)	
Is product sold by manufact	turer's exclusive distr	ributor?	No		om mfr?	,					0.3		4	2.5		1
Has FDA granted waiver/exc	ception/exemption for	r product?	No	lf	yes, attach docu	imentation	from FDA.			Box/Carton/Bundle/						
			GTIN PRODUCT INFO							Inner Pack:						
				Saleable						Case:	7.6	13.5	5	10.5		24
			Level	Unit			Qua	antity (	GTIN-14	Pallet:						
Serialized?	Yes		X Item		<b>X</b> 2D	Lir	near í	1 0	00331722133012							
If not, when?			Box/Carton/Bundle/Inner Pac		2D		near	_		UPC:	Case:					
Items aggregated?	Yes	-  -	X Case Pallet	x	X 2D 2D			24 1	10331722133019		Carton:					
			Panel	+	2D 2D		near			.00	T INFORMATION			WHOLESAL	ER USE ON	LY:
					2D 2D		near									
					2D	Lir	near			Regular Cost			Vendor #:			
					2D	Lir	near			Invoice Cost (WAC)		\$33.88	Whsl. Code			
										Federal Excise Tax	Per Unit of Sale		Fineline Co	de:		
										As of date:			-			
			Attach copy of SAFETY D		(DS) or non bazo	d letter DA		ERT I AP					I			
*Diseas provide only addition	nal information on pa	ne 2	Allacit copy of SAFETY L	AIA SHEET (S	UT NOT Hazal				op Ship Only.	Signa						
		90 L.				ace new h		griated DI	op only only.	Jight	uio.					

## HDA

## **Standard Pharmaceutical Product Information (Page 2)**

	Inated Drop Ship Only Products, Please Use Page 3						
MATERIAL	HAZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply):							
a. Cytotoxic? No	SDS Hazard Classification						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?							
Is the product a CA Prop 65 carcinogen? No	X Organic Corrosive						
Is the product a CA Prop 65 reproductive toxicant? No	Inorganic Oxidizer						
Does the product label bear a CA Prop 65 warning? No	Steroid/Androgen Contact Hazard						
	Contact nazaru						
c. Contact Hazard? No	Aerosol Class; Identify NFPA Storage Level:						
	Aerosol Class, identify INFPA Storage Level:						
d. Does this product require special clean-up instructions? No							
(If yes, attach SDS with special instructions.)	Is the product a NIOSH hazardous drug? No						
e. Does the product contain DEHP? No	If yes, indicate which:						
Is this product regulated for shipment by DOT or IATA? No							
(if yes, answer a-e below and provide SDS)							
a. UN/Identification Number							
b. Proper Shipping Name	Hazardous Waste Identification						
c. DOT Hazard Class	EPA Hazardous Waste Code:						
d. Packing Group							
e. Inhalation Hazard? No							
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS						
Passenger	Is there a REMS on this product? No						
Cargo	If Yes, is it managed with a pharmacy registry?						
Passenger & Cargo	Website URL:						
Is this a reportable quantity? No							
RQ Threshold:	Comments / Details: (For example, iPledge program?)						
Is this a marine pollutant? No	Commonito' Detailo. (r or oxample, in reago program.)						
Is this product shipped utilizing an authorized DOT exception or Special Permit?							
(if yes, identify method below)	REMS: No						
	REMS: No REMS Program Manager Name: Phone: P						
Limited Quantity							
Consumer Commodity, ORM-D	Supplier Manages REMS registry exclusively:						
Small Quantity (49 CFR 173.4)	Wholesale distributor support:						
Special Permit; DOT-SP	Provider Name:						
Special Provision (listed in Column 7 of 49 CFR 172.101);	Site Enrollment Number assigned DEA #:						
SP#	by Supplier: PCPDP #:						
	NPI #:						
ADD'L STORAGE INFORMATION							
Is the Product	Comments						
Controlled Substance? No							
Controlled by State(s)? No	Registry: No						
ARCOS Reportable? No	Registry Program Contact Name: Phone:						
Schedule No. (inc. N for non-narcotic)	Comments						
Controlled Substance Code							
Listed Chemical (List I or II) No	RETURN INSTRUCTIONS						
If yes, indicate which:							
Is it a scheduled listed chemical product?: No	Contact tel. # if product received damaged: 732-529-0430						
CLASS OF TRADE RESTRICTION:	Is product returnable for credit: Yes						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	URL/Link to returns policy: contact - customerservice@camberpharma.com						
Restricted to retail pharmacy only: No	Special regulations or returns requirements for this product in certain states? No						
Restricted to hospital, clinics, and physician offices only: No	If so, which states? Other requirements? Comments?						
Restricted from US territories? (explain in comments) No							
Comments:							
MISCELLA	NEOUS NOTES and/or Image of Product Barcode:						



## **Standard Pharmaceutical Product Information (Page 3)**

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if	
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 #:	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:	
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:         Order receipt method:       Phone:         Fax:       Fax #:         EDI:       Overnight Fees apply:         Other fees apply:       Image: Content of the content of th
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?