

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014						Introduction	Туре:	Post Launch Change		Final Version			Date:	4/18	3/2017
			PRODUCT INFORMAT							SPECIAL HANDL	ING AND ST	ORAGE REQ	UIREMENTS	5*	
Company Name:	Camber Pharmaceuti	cals				Арг	olication:	ANDA	a. Temperature – Indi	cate the USP temper	ature range f	for this produ	ıct.		
Application Number for ND	A/ANDA/BLA (drug); I	PMA/510(k)(med devic	e):	203835						ature Range				en 20 and 25	5 C (68° – 77° F
DUNS:	82-667-4775		•						Other T	emperature Range Re	auirement				
Proprietary Name (If Applica		Name: Losarta	n Potassium Tablets 50MG 90	СТ						rite in)	squiromont				٦
Selling Unit NDC:	31722-701-90		Individual Unit NDC:		-701-90	UPC:	331722701	907							
UDI	NA		CVX Code:			MVX Code:	NA		Is this p	product to be shipped t	to customers	on ice?		No	
Description:	White to off-white over	I tablets imprinted with '	'6' on upper and 'l' on lower							product to be shipped t				No	-
															_
Active Ingredient(s):		Losartan Potassium							b. Contact for temper	ature excursion ques	stions:				
									Name:			Soma Raju			
URL for Additional Product I Address:		www.camberpharma.co	om			duana 2:	-		Numbe			732-529-04	-		
City:	Piscataway	1031 Centennial Avenue			Address 2:			Group	E-mail:		somaraju@	heterousa.co	m		
Key Contact:	Customer Service	· ·			Email: customerservice@camberpharma.com			c. Special regulations	for product in any s	states?			No		
Phone Number:	732-529-0430				Fax: 732-562-8788			Special returns requirements for this product? No					-		
Product Therapeutic Classif															-
									d. Store product (unit	of sale) upright?				No	
ADDITIONA	AL PRODUCT INFORM	ATION			PROD	DUCT DESCRI		MATION		product (unit of sale	e) from light?	,		No	-
Is the Product									e. Shelf life:	•	-			24	Months
a legend device?		No				00				helf life at launch (if	different):				Months
reverse numbered?		No	-	Size:		90									-
co-licensed?		No	[]	Stren	nth.	50 mg					ORDER INFO	RMATION			
Is the Product		Direct-Ship Only	[]	Stren	ju i.	30 mg									
Is the Product		Unit of Use	_	Dosa	e Form:	oral solid	tablet		Unit of				NDC selling	unit?	
										Bottle		1 box of 24		016-1-1	
If Unit Dose, is item bar code	ed to unit dose for hosp	ital scanning?							x	Box/Carton Ampule		(Write-in, e	.g. 1 Box of 1	0 Vials)	
If Unit Dose NDC, indicate N	JDC here			Produ	ct Shape:	Oval				Glass		Minimum o	rder quantit	0	Yes
I Offit Dose NDC, indicate N	DO Here.		4							Tube		Willing	idei quanti		163
Country of Origin		India	1	Produ	ct Color:	White				Vial Liquid Sgl					
Is this product covered unde	ar the Trade Agreements	Act (TAA)2	-	Brodu	ct Imprint:	6/1				Vial Liquid Multi		If Yes, how	many of wh	ich package	type?
is this product covered unde	and made Agreementa	No.	_	Tiout	ot imprint.	0/1				Vial Powder Sql			Each		
										Vial Power Multi		24	Inner/Cartor	n/Pack	
			FOR GENERIC DRUG PRO							Other: Write In	-		Case		
			FOR GENERIC DRUG PRO	000013											
					Authorized	d Generic	*If Authorize	ed Generic, other section		PHAR	RMACY ORD	ER / BILL UN	IT		
I. Orange Book Rating:	AB						fields are ne	ot applicable	Rec. sell unit to customer? Rx billing unit to pharmacy:						
II. Generic Equivalent to What		Cozaar										Tex bining c	Each	ucy.	
									(Write-in, e.g. 1 Vial)				Gram		
		DRUG SUPP	PLY CHAIN SECURITY ACT (DSCSA) INFORMA	TION								Milliliter		
			No		_				-						
Does supplier meet DSCSA Is product exempt from DSC		urer?	Yes	GLN:						ITEM A	ND PACKING	SINFORMAT			
If yes, select exemption:	JOA:		110								Dime	nsions (US n	nsmts.)	Volume	
Other exemption - Write in:	:							1		Weight Lbs.	Depth	Height	Width	(Cube)	# Pieces:
Is product repackaged?			No	lf Yes, wa	s original pro	oduct purchas	ed direct	-	Item:	0.05		3	1.5		
Is product sold by manufact			No	from mfr						0.00		3	1.5		
Has FDA granted waiver/exc	ception/exemption for	product?	No	If yes, att	ach documer	ntation from FE	DA.		Box/Carton/Bundle/						
			GTIN PRODUCT INFORM						Inner Pack:						
				Saleable					Case:	2.3	10	4.5	7	0.182	24
			Level	Unit			Quantity	GTIN-14	Pallet:						
Serialized?	Yes	x	Item	x	2D	Linear	1	00331722701907							4416
If not, when?			Box/Carton/Bundle/Inner Pack		2D	Linear			UPC:	Case:					
Items aggregated?	Yes	x	Case	x x	2D	Linear	24	20331722701901		Carton:					
			Pallet		2D	Linear									
					2D	Linear			COS	INFORMATION			WHOLESAL	ER USE ONI	LY:
					2D	Linear						.			
					2D 2D	Linear			Regular Cost			Vendor #:	4.		
		L		I	2D	Linear			Invoice Cost (WAC) (Federal Excise Tax P		\$17.00	Whsl. Code Fineline Co			
└────									As of date:	er onit or sale	1	rinenne Co	ue.		
									715 01 0016.			1			
			Attach copy of SAFETY DAT	A SHEET (SDS) or	non hazard le	etter. PACKAGE	E INSERT, LA	BEL AND PHOTO OF PR	ODUCT PACKAGING and	BARCODE					
			, maon oopy of on a LIT DAT						SESSI MORAGINO and I						
*Please provide any addition	nal information on page	e 2.			Se	e new p. 3 for	Designated F	Drop Ship Only.	Signatu	ire:					



Standard Pharmaceutical Product Information (Page 2)

	gnated 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?						
	Organic Corrosive					
Is the product a CA Prop 65 carcinogen? No						
Is the product a CA Prop 65 reproductive toxicant?	Inorganic Oxidizer					
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard					
c. Contact Hazard? No	Aerosol Class; Identify NFPA 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?					
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?						
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS					
Passenger	Is there a REMS on this product? No					
	If Yes, is it managed with a pharmacy registry? Website URL:					
Passenger & Cargo	Website UKL:					
Is this a reportable quantity? No						
RQ Threshold:	Comments / Details: (For example, iPledge program?)					
Is this a marine pollutant? No						
Is this product shipped utilizing an authorized DOT exception or Special Permit?						
No (if yes, identify method below)	REMS:					
Limited Quantity	REMS Program Manager Name: Phone:					
Consumer Commodity, ORM-D	Supplier Manages REMS registry exclusively: No					
Small Quantity (49 CFR 173.4)	Wholesale distributor support: No					
Special Permit; DOT-SP	Provider Name:					
Special Provision (listed in Column 7 of 49 CFR 172.101);	Site Enrollment Number assigned DEA #: No					
SP#						
	NPI #: No					
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	1					
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 No	URL/Link to returns policy: contact - customerservice@camberpharma.com					
Restricted to retail pharmacy only: Yes	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:						
Comments.						
MISCELL	ANEOUS 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: Yes a. EDI Yes b. Autofax No c. Fax Yes d. Phone only No e. Supplier Web Site only No Minimum Order Quantity: case pack	Purchase order daily receipt cut off time by supplier Cut off time: 2:30PM Eastern Shipping lead time of PO: 24/48 Hours Days Ships same day for next day receipt: No No
Supplier's Customer Service Number: 732-529-0430 x466 x465 x467 x470 Contracted 3PL company / contact #: Name: Phone: Phone: Expedited Freight Charges or Other Designated Drop Ship Fees:	Ships for second day receipt: No Ships regular ground for 3-10 days receipt: Yes Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: No	Overnight receipt available: Yes
Drop Ship service fee billed with each order: No	PO Receipt cut off time: 2:30PM Eastern
Drop Ship miscellaneous fees billed: No Comments:	Days of week overnight is available: X Monday X Tuesday X Wednesday X Thursday X Friday
Olano of Tarala Destrictions	Priority Overnight receipt available: Yes
Class of Trade Restriction: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No Restricted to retail pharmacy only: Yes Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No Comments:	Saturday Overnight receipt available: No Saturday Overnight receipt available: No PO Receipt Cut off time: No PO Receipt Cut off time: Po Receipt Cut off time: Order receipt method: Phone: No Fax: Yes EDI: Yes Overnight Fees apply: Yes Other fees apply: No
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	Contact # if product is received damaged: 732-529-0430 Is product returnable for credit: Yes URL/Link to returns policy:
Miscellaneous Notes:	
	ADDITIONAL INFORMATION Is product order for scheduled patient procedure? No
	Is product order for restocking purposes? No