

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014						Introduction	Туре:	Post Launch Change]	Final Version			Date:	5/9/	2017	
			PRODUCT INFORMA	TION						SPECIAL HANDL	ING AND ST	ORAGE REQ	UIREMENTS	*		
Company Name:	Camber Pharmaceutic	als				App	plication:	ANDA	a. Temperature – Indio	ate the USP temper	ature range f	for this produ	ict.			
Application Number for ND	A/ANDA/BLA (drug); P	MA/510(k)(med devi	ce):	203311			·			ature Range	•			en 20 and 25	C (68° – 77° F	
DUNS:	82-667-4775								Other Te	emperature Range Re	equirement					
Proprietary Name (If Applica	able) and Established N	ame: Valsa	rtan Tablets USP 160MG 90CT	[rite in)					1	
Selling Unit NDC:	31722-747-90		Individual Unit NDC:	3172	2-747-90	UPC:	3317227479	905							-	
UDI			CVX Code:			MVX Code:			Is this p	oduct to be shipped t	to customers	on ice?		No	_	
Description: Yellow capsule shaped tablets, lower imprinted with '184' and upper with 'H'								Is this product to be shipped to customers on dry ice? No								
Active Ingredient(s): Valsartan							b. Contact for temperature excursion questions: Name: Soma Raju									
URL for Additional Product	Information.	www.camberpharma.	com						Number			732-529-042	23			
Address:	1031 Centennial Avenue				Address 2:				Group E			somaraju@heterousa.com				
City:	Piscataway	iscataway			State: NJ Zip: 08854											
Key Contact:	Customer Service	ner Service			Email: customerservice@camberpharma.com				c. Special regulations					No	-	
Phone Number:	732-529-0430				Fax: 732-562-8788				Special	returns requirements	for this produ	ct?		No	_	
Product Therapeutic Classif	fication:															
		TION	_		DROD	DUCT DESCRI		MATION	d. Store product (unit					No	-	
	AL PRODUCT INFORM	ATION		-	PROL	JUCT DESCRI	PTION INFOR	MATION		product (unit of sale	e) from light?			No		
Is the Product									e. Shelf life:					24	Months	
a legend device?		No	_	Size:		90			Initial s	helf life at launch (if	different):				Months	
reverse numbered? co-licensed?		No No	-								ORDER INFO	RMATION				
Is the Product		Direct-Ship Only	-	Stren	ngth:	160 mg						NillA HON				
Is the Product		Unit of Use	-			Oral and			Unit of S	Sale		What is the	NDC selling	unit?		
			-	Dosa	ige Form:	Oral solic	labiel			Bottle		1 box of 12				
If Unit Dose, is item bar code	ed to unit dose for hospit	al scanning?							X	Box/Carton		(Write-in, e	.g. 1 Box of 1	0 Vials)		
		ar obanning.		Prod	uct Shape:	capsule				Ampule						
If Unit Dose NDC, indicate N	DC here:									Glass		Minimum o	rder quantity	?	Yes	
Country of Origin		India	-	Prod	uct Color:	yellow				Tube Vial Liquid Sgl						
										Vial Liquid Multi		If Yes, how	many of whi	ch package	type?	
Is this product covered unde	er the Trade Agreements	Act (TAA)? No		Prod	uct Imprint:	184' on u	pper/'H' on low	ver		Vial Powder Sql			Each		.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
			—							Vial Power Multi		12	Inner/Carton	/Pack		
-										Other: Write In	_		Case			
			FOR GENERIC DRUG PR	ODUCTS												
					Authorized	d Generic	*If Authorize	ed Generic, other section		PHAR		ER / BILL UN	п			
I. Orange Book Rating:	fields are not a					Rec. sell unit to customer? Rx billing unit to pharmacy:										
II. Generic Equivalent to What		Diovan									٦	Tex binning u	Each	ucy.		
•••••									(Write-in, e.g. 1 Vial)				Gram			
		DRUG SUP	PPLY CHAIN SECURITY ACT ((DSCSA) INFORMA	ATION								Milliliter			
Does supplier meet DSCSA	definition of manufactu	irer?	Yes	GLN:						ITEM A	ND PACKING	INFORMAT	ION			
Is product exempt from DSC			No	GEN.					ITEM AND PACKING INFORMATION							
If yes, select exemption:										Weight Lbs.		nsions (US n		Volume	# Pieces:	
Other exemption - Write in:	:									Meigin Ebs.	Depth	Height	Width	(Cube)	#110003.	
Is product repackaged? Is product sold by manufact	unaria avaluatua diatrik		No No	If Yes, wa from mfr		oduct purchas	ed direct		Item:	0.15		4	1.875			
Has FDA granted waiver/exc			No			ntation from FI	Δ		Box/Carton/Bundle/			-				
				ii yos, au			**		Inner Pack:	2.15	8	4.375	6	0.122	12	
			GTIN PRODUCT INFORI						Case:	10.7	13.625	10.125	9.375	0.748	48	
				Saleable						10.7	15.025	10.125	3.375	0.740	40	
			Level	Unit			Quantity	GTIN-14	Pallet:							
Serialized?	Yes	x		<u>×</u>		Linear	1	00331722747905 10331722747902		Casai		L				
If not, when? Items aggregated?	Yes	x		x x x		Linear	12 48	30331722747902	UPC:	Case: Carton:						
nems aggregateu :	185	×	Pallet		2D 2D	Linear	40	00001122141000		Joanon.						
				──┤ ├──	2D 2D	Linear			COST	INFORMATION			WHOLESAL	ER USE ONI	_Y:	
					2D	Linear										
					2D	Linear			Regular Cost			Vendor #:				
					2D	Linear			Invoice Cost (WAC) (\$		\$35.66	Whsl. Code				
									Federal Excise Tax Pe	r Unit of Sale		Fineline Co	de:			
									As of date:			-				
					r non horsed !-	Hor BACKAC				ARCODE		1				
*Please provide any addition	nal information on nam	2	Attach copy of SAFETY DAT	A SHEET (SUS) 0												
*Please provide any additional information on page 2. See new p. 3 for Designated Drop Ship Only. Signature:																



Standard Pharmaceutical Product Information (Page 2)

	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?	SDS Hazard Classification						
Is the product a CA Prop 65 carcinogen? No Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning?	Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard						
c. Contact Hazard? No d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) e. Does the product contain DEHP? No	Aerosol Class; Identify NFPA Storage Level:						
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 c. DOT Hazard Class	Hazardous Waste Identification EPA Hazardous Waste Code: NA						
d. Packing Group e. Inhalation Hazard?							
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS						
Passenger Cargo Passenger & Cargo	Is there a REMS on this product? No If Yes, is it managed with a pharmacy registry? Website URL:						
Is this a reportable quantity? No RQ Threshold:	Comments / Details: (For example, iPledge program?)						
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) Special Permit; DOT-SP	REMS: REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: No Wholesale distributor support: No Provider Name: No						
Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Site Enrollment Number assigned DEA #: No by Supplier: PCPDP #: No NPI #: No						
ADD'L STORAGE INFORMATION							
Is the Product No Controlled Substance? No Controlled by State(s)? No ARCOS Reportable? No	Comments Registry: No Registry Program Contact Name: Phone: Phone						
Schedule No. (inc. N for non-narcotic) Controlled Substance Code	Comments						
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:							
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: a. EDI b. Autofax No Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time: 2:30PM Eastern
b. Autolax No Pax Number. c. Fax Yes Fax Number: d. Phone only No Phone No.:	Shipping lead time of PO: 24/48 Hours Days
e. Supplier Web Site only No Site Address: Minimum Order Quantity: case pack Supplier's Customer Service Number: 732-529-0430 x466 x465 x467 x470 Contracted 3PL company / contact #: Name: Phone:	Ships same day for next day receipt: No Ships for second day receipt: No Ships regular ground for 3-10 days receipt: Yes
Expedited Freight Charges or Other Designated Drop Ship Fees:	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
	Priority Overnight receipt available: Yes
Class of Trade Restriction:	PO Receipt Cut off time: 2:30PM EST
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 PO Receipt Cut off time: Phone: No Order receipt method: Phone: Yes Fax: Yes Fax #: EDI: Yes Overnight Fees apply: Yes Other fees apply: No
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician/Clinic DEA #: Physician/Clinic Specialty: Miscellaneous Notes:	Contact # if product is received damaged: 732-529-0430 Is product returnable for credit: Yes URL/Link to returns policy:
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure? No Is product order for restocking purposes? No