

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014					Introduction Type	Post Launch Ch	nange		Final Version			Date:	7/9	2021	
			PRODUCT INFORMATION	ON					SPECIAL HANDL	ING AND STO	RAGE REQ	UIREMENTS	*		
Company Name:	Camber Pharmaceuti	cale			Applicat	ion: ANDA	Δ	a. Temperature – Indio	eate the USB temper	aturo rango fe	or this produ	ıct			
Application Number for ND			1	203311/S-012	Аррион	7111071	,		ature Range	ature range it			en 20 and 25	C (68° – 77°	
		i iii/vo ro(k)(iiica acvice)	-	20001170 012				· ·	=		COMMONICA !	toom bottee	on to and to	70 (00 11	
DUNS:	82-667-4775	her .	T						emperature Range Re	equirement				-	
Proprietary Name (If Applical Selling Unit NDC:	31722-154-90	Name: Valsartar	n Tablets USP 320MG 90CT		UPC: 33°	722154901		(W	rite in)						
UDI	31722-134-90		CVX Code:		MVX Code:	722134901		la thia a			-:2		No		
-			!					•	roduct to be shipped t					_	
Description:	Oral Solid Tablet, dar	k grey violet, capsule sha	ped, concave punches, embos	ssed with 'H' on Lower pu	unch and '185' on upper pu	nch with corresponding die	es	Is this p	roduct to be shipped t	o customers o	n dry ice?		No	_	
		he i													
Active Ingredient(s):	ive Ingredient(s): Valsartan						b. Contact for tempera Name:	ature excursion ques		Soma Raju					
LIBI for Additional Braduat I	RL for Additional Product Information: www.camberpharma.com								Number:			732-529-0423			
Address:	t Information: www.camberpnarma.com 800 Centennial Avenue Address 2:						Group E		somaraju@heterousa.com						
City:	Piscataway	uc		State:	NJ Zip:	08854		Oroup I	- man.		30maraja e	ictorousu.coi			
Key Contact:	Customer Service			Email:	customerservice@cam	berpharma.com		c. Special regulations	for product in any s	tates?			No		
Phone Number:	732-529-0430			Fax:	732-562-8788			Special regulations for product in any states: No No					-		
Product Therapeutic Classifi	ication:								•	•				-	
								d. Store product (unit	of sale) upright?				No		
ADDITIONA	AL PRODUCT INFORM	IATION	1		PRODUCT DESCRIPTION	NINFORMATION			product (unit of sale	e) from light?			No	_	
Is the Product			1					e. Shelf life:	.	,			24	Months	
a legend device?		No							helf life at launch (if	different):			24	Months	
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co-licensed?		No								ORDER INFOR	RMATION				
Is the Product		Direct-Ship Only		Strength:	320mg										
Is the Product		Unit of Use		Decade Form	m: Oral Solid Tab	ot		Unit of	Sale		What is the	NDC selling	unit?		
				Dosage Forr	iii. Olal Solid Tab	el		x	Bottle		1 bottle of 9				
If Unit Dose, is item bar code	nd to unit dose for hose	ital scanning?							Box/Carton		(Write-in, e	g. 1 Box of 1	0 Vials)		
		No No		Product Sha	ape: Capsule				Ampule						
If Unit Dose NDC, indicate NI	DC here:								Glass		Minimum o	rder quantity	/?	Yes	
				Product Cole	or: Dark grey viole	et .			Tube						
Country of Origin		India							Vial Liquid Sgl Vial Liquid Multi		K V		ich package	4	
Is this product covered under	r the Trade Agreement	s Act (TAA)? No		Product Imp	rint: 'H'/'185'				Vial Powder Sql			Each	icii package	typer	
		140							viai i owdei oqi		12				
									Vial Power Multi			Inner/Carton	/Pack		
<u> </u>]						Vial Power Multi Other: Write In			Inner/Cartor Case	/Pack		
			FOR GENERIC DRUG PROD	DUCTS					Vial Power Multi Other: Write In	7		Inner/Cartor Case	/Pack		
			FOR GENERIC DRUG PROD	DUCTS					Other: Write In			Case	/Pack		
			FOR GENERIC DRUG PROD			Authorized Generic, other	section		Other: Write In	RMACY ORDE	R/BILL UN	Case	n/Pack		
I. Orange Book Rating:	AB		FOR GENERIC DRUG PROD			Authorized Generic, other	section	Rec. sell unit to custo	Other: Write In	RMACY ORDE		Case			
I. Orange Book Rating: II. Generic Equivalent to Wha		Diovan	FOR GENERIC DRUG PROD				section	Rec. sell unit to custo	Other: Write In	RMACY ORDE		Case			
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Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): **SDS Hazard Classification** a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No 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 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? No REMS or REGISTRY RESTRICTIONS Is the product restricted for air shipment? If so, indicate restriction: Passenger Is there a REMS on this product? Cargo If Yes, is it managed with a pharmacy registry? Passenger & Cargo Website URL: Is this a reportable quantity? RQ Threshold: Comments / Details: (For example, iPledge program?) Is this a marine pollutant? Nο Is this product shipped utilizing an authorized DOT exception or Special Permit? (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 by Supplier: No SP# PCPDP #: NPI#: No ADD'L STORAGE INFORMATION Is the Product.. Comments Controlled Substance? No Controlled by State(s)? No Registry: ARCOS Reportable? No Registry Program Contact Name: Schedule No. (inc. N for non-narcotic) Comments Controlled Substance Code Listed Chemical (List I or II) No RETURN INSTRUCTIONS If yes, indicate which: 732-529-0430 Is it a scheduled listed chemical product?: No Contact tel. # if product received damaged: CLASS OF TRADE RESTRICTION: Is product returnable for credit: 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: MISCELLANEOUS NOTES and/or Image of Product Barcode:



Standard Pharmaceutical Product Information (Page 3)

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	Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax c. Fax d. Phone only e. Supplier Web Site only Fax Number: Phone No.: Site Address:	Shipping lead time of PO: Hours Days Ships same day for next day receipt:
Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	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:	Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: Monday
Comments:	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: 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:	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? Is product order for restocking purposes?