

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

Version 2021						Introduction 1	Гуре:	Post Launch Change		x Final	Version			Date:	7/12/	2021	
PRODUCT INFORMATION									SPECIAL HANDLING AND STORAGE REQUIR					REMENTS*			
Company Name: Jubilant Cadista Pharmaceuticals Inc. Application: ANDA								a. Temperature – Indicate the USP temperature range for this product.									
Application Number for NDA/ANDA/BLA (drug); PMA/510k/med device):  20356  Application Number for NDA/ANDA/BLA (drug); PMA/510k/med device):  20356  Temperature Range  Controlled Room – between 20 and 25 C (68° – 77° F)																	
Medical Device Class, if applicable:																	
DUNS:	022490515									Other Tempera	ature Range R	Requirement					
Proprietary Name (If Applicable) a		ame: Valsar	tan Tablets							(write in)	-						
Selling Unit NDC:	59746-361-90		Unit of Use NDC:			UPC:	3-5974	46-361-90-7		Notes							
UDI			CVX Code:			MVX Code:											
Description: Valsartan 80mg 90ct Tablet									il	le this product	to he shinned	to customers on id	ce?		No		
											No						
Active Ingredient(s): Valsartan													,				
										b. Contact for temperature excursion questions:							
URL for Additional Product Inform													mer Service				
Address:	207 Kiley Drive	e				Address 2:			Number:				(800) 313-4623				
City:	Salisbury				State:	MD		21801	Group E-mail:				customer.service@cadista.com				
Key Contact:	Jackie Emershaw				Email:	Jackie.Emersh		<u>ıbl.com</u>	ll <u> </u>	marial namedations for unadout in account 20							
Phone Number:	(410) 912-3722				Fax:	(215) - 443 - 9646			c. Special regulations for product in any states?						No		
Product Therapeutic Classification	Antihypertensive									Special returns	s requirements	s for this product?			No		
	ADDITI	ONAL PRODUCT IN	FORMATION			PRODUCT	DESCRI	IDTION INFORMATION							NI.		
	ADDITI	ONAL PRODUCT IN	FORMATION			PRODUCTI	DESCRI	IPTION INFORMATION	d. Store produ	uct (unit of sale	e) upright?				No		
The product is?			Is the Product	Direct-Ship C	Only					Protect produ	ct (unit of sa	le) from light?			No		
a legend device?	-	No Is the Product Neither		Neither	Size:		90 count		e. Shelf life:				24			Months	
if yes, enter class #		Orphan Drug Status					00		Initial shelf lif	e at launch (i	f different):				Months		
a product kit? if yes, list NDCs of	No FDA Annaugi Status				Strength:		80mg				ORDER INFORM	MATION					
component parts			FDA Approval Status					TABLET				ORDER IN ORM	IATION				
reverse numbered?		No				Dosage Forn	m:	17.0221		Unit of Sale			What is the	NDC selling	unit?		
co-licensed?		No	Allergens Present							X Bottl	e		1 bottles of				
latex-free?		Yes				Burnelous Observ		Round, Biconvex		Box/	Carton		(Write-in, e	g. 1 Box of 1	) Vials)		
preservative-free?		No				Product Sha	ipe:			Amp	ule			-			
correctional institution block?		Yes				Product Cole	or:	Peach		Glas	s		Minimum o	rder quantity	?	Yes	
opioid?		No				r roduct con	OI .			Tube							
Cannabinoid?		No	Country of Origin	IN		Product Imp	rint:	C3 / C			Liquid Sgl						
If Unit Dose, is item bar coded to	unit dose for										Liquid Multi			many of whi	ch package	type?	
	hospital scanning? Is this product covered under the If Unit Dose, indicate NDC here: Trade Agreements Act (TAA)?							Vial Powder Sql			48 Each						
If Unit Dose, indicate NDC here:			Trade Agreements Act (	IAA)!	No						Power Multi r: Write In			Inner/Carton Case	/Pack		
			FOR GENERIC DRUG PRO	DUCTE		_			<u>L</u>	Ottle	i. wille ili			Case			
			FOR GENERIC DRUG PR	DDUCTS													
					Δι	uthorized Generic	*If Aut	thorized Generic, other			PHA	ARMACY ORDER	/ BILL UNIT				
					unonzed Generic		n fields are not applicable	Dec cell unit	to ouetomor?	• • • • •							
I. Orange Book Rating:  II. Generic Equivalent to What Brand?:  Diovan								Rec. sell unit to customer?				Rx billing unit to pharmacy:					
II. Generic Equivalent to What Brand?:							1 bottles of 90 tablets (Write-in, e.g. 1 Vial)				x Each Gram						
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION									(vviite-iii, e.g. 1 viai) Milliliter								
			,	,					1					1			
Does supplier meet DSCSA defin	ition of manufactu	rer?	Yes		GLN:	8902805000006					ITEM	AND PACKING IN	NFORMATIO	N			
Is product exempt from DSCSA?			No														
If yes, select exemption:					GCP:	0359746						Dimensi	ons (US msr	nts.)	Volume	Saleable #	
Other exemption - Write in:									'	w	eight Lbs.	Depth	Width	Height	(Cube)	Pieces	
Is product repackaged?			No		If yes, was o	riginal product			Item/Each:		0.40				45.00		
Is product sold by manufacturer's	s exclusive distrib	utor?	No			irect from mfr?					0.12	1.87	1.87	4.37	15.28	1	
Has FDA granted waiver/exception	on/exemption for p	roduct?	No		Provide sour	ce manufacturer fo	or repac	ckaged product	Box/Carton/B	undle/					0.00		
If yes, attach documentation fro	m FDA.								Inner Pack:						0.00		
									Case:		8.4	15.63	11.89	6.1	1133.63	48	
		GTII	N AND HIBCC PRODUCT I	IFORMATION													
Colooble Unit of Manager	,	Salaahia Oosaaliis	LUDOO		0.71	151.44		Hallact Land OTINI 44	Pallet:						0.00		
Saleable Unit of Measure	8	Saleable Quantity	HIBCC			N-14		Unit of Use GTIN-14									
X Item/Each Box/Carton/Bundle/Inner Pack				59746361907	746361907			COST INFORMATION				WHOLESALER USE ONLY:					
X Case		48			403	59746361905	-			COST IN	OKWATION			WITOLLSALI	IN USE ONE	1.	
Pallet		40			403				Regular Cost				Vendor #:				
1 0.00							-		Invoice Cost (			\$21.53	Whsl. Code	#:			
												7200	Fineline Co				
									As of date:								
			Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza			T, LABEL AND PHOTO OF F			RCODE.						
*Please provide any additional inf	formation on nade	2				See new n 3 for	Design	nated Dron Shin Only		Signature:							



Version 2021

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For Designated 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? Nο Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? No Inorganic Oxidizer Does the product label bear a CA Prop 65 warning? Steroid/Androgen Contact Hazard No c. Contact Hazard? No Does the product have an Aerosol class? If yes, identify NFPA Storage Level: d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) NFPA Storage Level: e. Does the product contain DEHP? No Is this product regulated for shipment by DOT? No Is the product a NIOSH hazardous drug? No (if yes, answer a-e below and provide SDS) If yes, indicate which: a. UN/Identification Number b. Proper Shipping Name **Hazardous Waste Identification** c. DOT Hazard Class d. Packing Group EPA Hazardous Waste Code: Waste Characteristics e. Inhalation Hazard? No 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 Is there a REMS on this product? b. Proper Shipping Name c. DOT Hazard Class If Yes, is it managed with a pharmacy registry? d. Packing Group Website URL: e. Inhalation Hazard? No Is the product restricted for air shipment? If so, indicate restriction: No Med Guide Required No Passenger Limited Distribution Requirement No Cargo Comments / Details: (For example, iPledge program?) Passenger & Cargo Is this a reportable quantity? REMS: RQ Threshold: REMS Program Manager Name: Phone Is this a marine pollutant? Nο Supplier Manages REMS registry exclusively: Is this product shipped utilizing an authorized DOT exception or Special Permit? Wholesale distributor support: (if yes, identify method below) Provider Name: DEA #: Site Enrollment Number assigned NCPDP# Limited Quantity Consumer Commodity, ORM-D NPI#: by Supplier: Small Quantity (49 CFR 173.4) Special Permit: DOT-SP Comments Special Provision (listed in Column 7 of 49 CFR 172.101); SP# Registry: Phone: Registry Program Contact Name: ADD'L STORAGE INFORMATION Comments Is the Product RETURN INSTRUCTIONS Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which: Contact tel. # if product received damaged: Schedule No. Is it a scheduled listed chemical product?: No Is product returnable for credit: CLASS OF TRADE RESTRICTION: URL/Link to returns policy: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes Restricted to retail pharmacy only: Special regulations or returns requirements for this product in certain states? Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) If so, which states? Other requirements? Comments? Comments: MISCELLANEOUS NOTES and/or Image of Product Barcode



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

### Version 2021

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  c. Fax  d. Phone only e. Supplier Web Site only  Minimum Order Quantity:  Supplier's Customer Service Number:  Contracted 3PL company / contact #:  Name: Phone:	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:						
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:  Drop Ship miscellaneous fees billed:  Comments:	PO Receipt cut off time:  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:  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:  Miscellaneous Notes:	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?						
	ADDITIONAL INFORMATION						
	Is product order for scheduled patient procedure? Is product order for restocking purposes?						