

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

Version 2021						Introduction Ty	vpe: Post Launch Cha	ange	x	Final Version			Date:	6/9/2	2023	
			PRODUCT INFORMA	TION						SPECIAL HAN	DLING AND STOP	RAGE REQUI	REMENTS*			
Company Name: Jubilant Cadista Pharmaceuticals Inc. Application:					on: ANDA		a. Temperature – Indic	ate the USP tempe	rature range for t	his product.						
Application Number for NDA/AN				20'	1170		·			iture Range	Controlled Room		and 25 C (68	° – 77° F)		
Medical Device Class, if applicat			· ·													
DUNS:	022490515								Other Te	mperature Range F	Requirement					
Proprietary Name (If Applicable) a	and Established Na	ame: Los	sartan Potassium Tablets						(wr	ite in)						
Selling Unit NDC:	59746-333-10		Unit of Use NDC:				3-59746-333-10-2		Notes							
UDI			CVX Code:			MVX Code:										
Description:	Losartan Potassiu	um 25mg 1000ct T	ablet							oduct to be shipped				No		
Is this product to be shipped to customers on dry ice? No																
Active Ingredient(s): Losartan Potassium																
URL for Additional Product Information: www.cadista.com/products/full-product-list									b. Contact for temperature excursion questions: Name: Customer Service							
URL for Additional Product Inform Address:	207 Kiley Drive	www.cadista.	com/products/full-produc	<u>t-list</u>	1	Address 2:			Name: Number			(800) 313-46				
City:	Salisbury					MD Zip: 21801			Group E-mail:				customer.service@cadista.com			
Key Contact:	Customer Service					customer.service@cadista.com					customer	Service ed	dista.com			
Phone Number:	(800) 313-4623				Fax:	N/A			c. Special regulations	for product in any	states?			No		
Product Therapeutic Classification	n:	Antihypertensive	9		1				Special r	eturns requirement	s for this product?			No		
	ADDITI	IONAL PRODUCT				PRODUCT D	ESCRIPTION INFORMATIO	ON	d. Store product (unit of sale) upright? No							
The product is?			Is the Product	Direct-Ship C	Inly				Protect	product (unit of sa	le) from light?			No		
a legend device?		No	Is the Product	Neither		Size:	1000 count		e. Shelf life:		-			24	Months	
if yes, enter class #			Orphan Drug Status			5120.			Initial sh	elf life at launch (if different):				Months	
a product kit?		No				Strength:	25mg									
if yes, list NDCs of			FDA Approval Status			J. J. J.	TABLETS				ORDER INFORM	NATION				
component parts reverse numbered?		No				Dosage Form	: TABLETS		Unit of S	ala		What is the	NDC selling	unit?		
co-licensed?		No	Allergens Present							Bottle		1 bottle of 10		unit:		
latex-free?		Yes	Allergens Fresent				Oval		~	Box/Carton			g. 1 Box of 10) Vials)		
preservative-free?		No				Product Shap	e:			Ampule		(J			
correctional institution block?		Yes				Product Color	Green			Glass		Minimum or	der quantity	?	Yes	
opioid?		No				Froduct Color				Tube						
Cannabinoid?		No	Country of Origin	US		Product Impri	nt: C / 333			Vial Liquid Sgl						
If Unit Dose, is item bar coded to u	unit dose for									Vial Liquid Multi			many of whi	ch package t	type?	
hospital scanning? If Unit Dose, indicate NDC here:			Is this product covered Trade Agreements Act (Vee					Vial Powder Sql Vial Power Multi		12	Each Inner/Carton	/Deels		
Il Unit Dose, Indicate NDC here.			Trade Agreements Act (TAA)	Yes					Other: Write In			Case	Pack		
			FOR GENERIC DRUG PR	ODUCTS		1							Case			
					Au	uthorized Generic	*If Authorized Generic, othe	ər		PH	ARMACY ORDER	/ BILL UNIT				
I. Orange Book Rating:	AB						section fields are not applic	able	Rec. sell unit to custor	ner?		Rx billing u	nit to pharma	acv:		
II. Generic Equivalent to What Brand?: Cozaar®						1 bottle of 1000 tablets				X Each						
						(Write-in, e.g. 1 Vial)				Gram						
		DRUG SUI	PPLY CHAIN SECURITY ACT	(DSCSA) INFOR	MATION								Milliliter			
			Ver			025074000000				1754			N			
Does supplier meet DSCSA definit Is product exempt from DSCSA?	tion of manufactur	rer?	Yes	_	GLN:	0359746000004				TIEN	I AND PACKING II	NFORMATIO	N			
						0000004					D	ana (112				
If yes, select exemption:					GCP:	0359746				Weight Lbs.		ions (US msn	,	Volume	Saleable #	
Other exemption - Write in: Is product repackaged?			No		If you was a	riginal product purcl	hanad		Item/Each:		Depth	Width	Height	(Cube)	Pieces	
Is product sold by manufacturer's	exclusive distribu	utor?	No		direct from n		laseu		nem/Each.	0.25	2.4	2.4	5.08	29.26	1	
Has FDA granted waiver/exception			No	-			repackaged product		Box/Carton/Bundle/					0.00		
If yes, attach documentation from									Inner Pack:					0.00		
									Case:	5.82	10.25	7.75	8.25	655.36	12	
			GTIN AND HIBCC PRODUCT I	NFORMATION						0.02	10.20	1	0.20	000.00		
Saleable Unit of Measure	-	Peleekie Orani'i	HIBCC		~~~	IN-14	Use of the OTHER		Pallet:					0.00		
X Item/Each	8	Saleable Quantity	HIBCC				Unit of Use GTIN-1	14								
Box/Carton/Bundle/Inner Pack								COST INFORMATION					WHOLESALI	ER USE ONL	Y:	
X Case		12			403	59746333100										
Pallet									Regular Cost			Vendor #:				
									Invoice Cost (WAC) (\$)		\$140.63	Whsl. Code				
	_											Fineline Co	de:			
	-								As of date:			4				
												1				
<u> </u>					(C) or non br		NSERT, LABEL AND PHOT					l				
*Please provide any additional infe	ormation on page	2	Attach copy of SAFETY D	ATA SHEET (SU	or non naza		Designated Drop Ship Only		RODUCT PACKAGING and Signatu							
Flease provide any additional info	ormation on page	۷.				See new p. 3 for L	Designated Drop Snip Only	у.	Signatul	e.						

HDA Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021 Fo	or Designated Drop Ship Only Products, Please Use Page 3
MAT	FERIAL HAZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? c. Contact Hazard? d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP?	No SDS Hazard Classification No Organic Corrosive No Inorganic Oxidizer No Steroid/Androgen Contact Hazard No Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No No NFPA Storage Level: Image: Contact Hazard
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	No Is the product a NIOSH hazardous drug? No If yes, indicate which: If yes, indicate which: Hazardous Waste Identification Image: No EPA Hazardous Waste Code: Waste Characteristics
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo Is this a reportable quantity? No RQ Threshold: Is this a marine pollutant? No Is this product shipped utilizing an authorized DOT exception or Special Permit? No (if yes, identify method below) Limited Quantity	No REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? No Website URL: No No Med Guide Required Limited Distribution Requirement No Comments / Details: (For example, iPledge program?) No REMS: Phone: Supplier Manages REMS registry exclusively: Phone: Wholesale distributor support: Provider Name: Site Enrollment Number assigned DEA #:
Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4) Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP# ADD'L STORAGE INFORMATION	by Supplier: NPI #: Comments
Is the Product Controlled Substance? No Controlled Substance Code Controlled by State(s)? ARCOS Reportable? No If yes, indicate which: Is it a scheduled listed chemical product?: CLASS OF TRADE RESTRICTION: No CLASS OF TRADE RESTRICTION:	No RETURN INSTRUCTIONS No Contact tel. # if product received damaged: Is product returnable for credit: URL/Link to returns policy:
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:	Yes Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments? SCELLANEOUS NOTES and/or Image of Product Barcode:



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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: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight receipt available: Image: Comparison of the co
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: EDI: Overnight Fees apply: Other fees apply:
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?