

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

	2021 Introduction Type: Post Launch Change							Change		x Final Version			Date:	7/12/	/2021	
			PRODUCT INFORMAT	TION						SPECIAL HAND	LING AND STOR	AGE REQUI	REMENTS*			
Company Name: Jubilant Cadista Pharmaceuticals Inc. Application: ANDA									a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/AN			e).	20	1170	7 (2)	7.11571	•			Controlled Room -		and 25 C (68	3° – 77° F)		
Medical Device Class, if applical		, no rouny(mod dorno	·)·							omporatoro rtango						
DUNS:	022490515								0	ther Temperature Range R	equirement					
Proprietary Name (If Applicable) a		ne· Losarta	an Potassium Tablets		1					(write in)	equirement					
Selling Unit NDC:	59746-335-90	ne. Losarta	Unit of Use NDC:			UPC: 3	3-59746-335-90-8		No.	otes						
UDI	007 10 000 00		CVX Code:			MVX Code:				0.00						
-												_			1	
Description:	Losartan Potassiun	n 100mg 90ct Tablet								this product to be shipped				No		
A ative Immediant(a).		Losartan Potassium							15	this product to be shipped	to customers on a	iry ice?		No	.]	
Active Ingredient(s):		LUSAITAII FUTASSIUIII							h Contact for to	mperature excursion que	ctions					
URL for Additional Product Inform	nation	ununu cadista con	n/products/full-product	t liet						imperature excursion que ame:		Customer Se	nvice			
Address:	207 Kiley Drive	www.cauista.com	1/products/Tuil-product	<u>t-iist</u>		Address 2:				ame: umber:		(800) 313-46				
City:	Salisbury				State:	MD Zip: 21801			Group E-mail:			customer.service@cadista.com				
Key Contact:	Jackie Emershaw	shaw			Email:	Jackie.Emershaw@jubl.com				roup L-man.		<u>customer.service(wcauista.com</u>				
Phone Number:	(410) 912-3722				Fax:	(215) - 443 - 9646			c Special regula	ations for product in any	states?			No	1	
Product Therapeutic Classificatio		Antihypertensive			-	(210) 110 0010				pecial returns requirements				No	-	
Froduct Therapeutic Classificatio	m. [Antinypertensive							٩	peciai returns requirements	ioi tiis pioduct?			INU]	
	ADDITIO	NAL PRODUCT INF	OPMATION			PPODUCT DE	ESCRIPTION INFORMAT	TION	d Store product	(unit of cale) unright?				No	1	
	ADDITIO	NAL I RODUCT INF		D: . 01:		T KODOCT DE	-OOKII HON INFORWAT	HON	· -	(unit of sale) upright?]	
The product is?			Is the Product	Direct-Ship C	Only					rotect product (unit of sal	e) from light?			No		
a legend device?		No	Is the Product	Neither		Size:	90 count		e. Shelf life:					24	Months	
if yes, enter class #			Orphan Drug Status				100		ln In	itial shelf life at launch (if	different):				Months	
a product kit?		No				Strength:	100mg				ORDER INFORM	ATION				
if yes, list NDCs of			FDA Approval Status				TABLETO				ORDER INFORM	ATION				
component parts						Dosage Form:	TABLETS			nit of Sale		What is the	NDC aallina			
reverse numbered? co-licensed?		No	All						0	X Bottle		1 bottle of 90		unitr		
latex-free?		No	Allergens Present				Oval, Scored			Box/Carton			g. 1 Box of 1	O Violo)		
preservative-free?		Yes No				Product Shape	e: Ovai, Scoled		_	Ampule		(vviite-iii, e.	y. I bux ui i	J viais)		
correctional institution block?		Yes					Green		_	Glass		Minimum o	der augntit	.2	Yes	
opioid?		No				Product Color	: Oreen		_	Tube		William Ci	uei quantity	•	163	
Cannabinoid?		No	Country of Origin	US			C / 335			Vial Liquid Sql						
If Unit Dose, is item bar coded to u		INO	Country or origin	-		Product Imprii	nt:			Vial Liquid Multi		If Yes how	many of wh	ich package	tyne?	
hospital scanning?	init dose for		Is this product covered u	nder the						Vial Powder Sql			Each	on paonago	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
If Unit Dose, indicate NDC here:	•		Trade Agreements Act (T	ГАА)?	Yes					Vial Power Multi			Inner/Cartor	/Pack		
	L		1 .							Other: Write In			Case			
			FOR GENERIC DRUG PRO	ODUCTS		*			_							
												1				
					Au	thorized Generic *	If Authorized Generic, ot	ther		PH/	RMACY ORDER	/ BILL UNIT				
I. Orange Book Rating:	cogtion fields are not applicable						section fields are not appl	olicable	Rec. sell unit to customer? Rx billing unit to pharmacy:							
									Rec. sell unit to		1 bottle of 90 tablets			X Each		
III. Generic Equivalent to What Bra		Cozzaar														
II. Generic Equivalent to What Bra		Cozzaar								le of 90 tablets						
II. Generic Equivalent to What Bra			Y CHAIN SECURITY ACT (I	DSCSA) INFOR	RMATION				1 bottl	le of 90 tablets			Each			
	nd?:	DRUG SUPPLY		DSCSA) INFOR					1 bottl	le of 90 tablets Vial)		X	Each Gram Milliliter			
Does supplier meet DSCSA defini	nd?:	DRUG SUPPLY	Yes	DSCSA) INFOR	RMATION GLN:	0359746000004			1 bottl	le of 90 tablets Vial)	AND PACKING IN	X	Each Gram Milliliter			
	nd?:	DRUG SUPPLY		DSCSA) INFOR		0359746000004			1 bottl	le of 90 tablets Vial)		X	Each Gram Milliliter			
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Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	nd?:	DRUG SUPPLY	Yes No	DSCSA) INFOR	GLN: GCP: If yes, was or	0359746			1 bottl	le of 90 tablets Vial)	Dimensio	X IFORMATION ons (US msn	Each Gram Milliliter			
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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



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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: PO Receipt cut off time: Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday					
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: Other Data Information Required to Process PO:	Priority Overnight receipt available: PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply: 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?					