

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

Version 2021						Introduction T	Гуре:	Post Launch Change		x	Final Version			Date:	6/9/	2023
PRODUCT INFORMATION					SPECIAL HANDLING AND STORAGE REQUIREMENTS*											
Company Name: Jubilant Cadista Pharmaceuticals Inc. Application: ANDA							a. Temperature – Indicate the USP temperature range for this product.									
Application Number for NDA/AN			e):	201	1170							Controlled Room		and 25 C (68	3° – 77° F)	
Medical Device Class, if applicable:																
DUNS:	022490515								,		mperature Range F	Requirement				
Proprietary Name (If Applicable) a		ame: Losarta	an Potassium Tablets			UPC:					te in)					
Selling Unit NDC: UDI	59746-335-90		Unit of Use NDC: CVX Code:			MVX Code:	3-5974	6-335-90-8	-	Notes						
											1					
Description: Losartan Potassium 100mg 90ct Tablet Is this product to be shipped to customers on ice? No																
Active Ingredient(s): Is this product to be shipped to customers on dry ice? No								1								
b. Contact for temperature excursion questions:																
URL for Additional Product Information: www.cadista.com/products/full-product-list							Name:				Customer Service					
Address:	207 Kiley Drive					Address 2:				Number:			(800) 313-46			
City:		Salisbury			State: Email:	MD		21801	Group E-mail: <u>customer.service@cadis</u>				adista.com	lista.com		
Key Contact: Phone Number:	(800) 313-4623	Customer Service			Fax:	customer.service@cadista.com N/A		iuista.com	c. Special regulations for product in any states?			No			1	
Product Therapeutic Classificatio		Antihypertensive				14/1			Special returns requirements for this product?				No			-
Special returns requirements for this product?									J							
	ADDIT	IONAL PRODUCT INF	FORMATION			PRODUCT I	DESCRI	PTION INFORMATION	d. Store prod	luct (unit o	f sale) upright?				No	1
The product is?			Is the Product	Direct-Ship O	nlv						product (unit of sa	le) from light?			No	i
a legend device?		No	Is the Product	Neither	,			90 count	e. Shelf life:	1101001	roduct (dilit or sa	ic) irom ngirt.			24	Months
if yes, enter class #			Orphan Drug Status			Size:				Initial sh	elf life at launch (i	if different):				Months
a product kit?		No				Strength:		100mg								
if yes, list NDCs of							T. D. ETO				ORDER INFORM	MATION				
component parts reverse numbered?		No				Dosage Forn	m:	TABLETS		Unit of S	ala		What is the	NDC selling	unit2	
co-licensed?		No	Allergens Present								Bottle		1 bottle of 9		unit	
latex-free?		Yes	7 mor gono i rocom			Described Observ		Oval, Scored			Box/Carton			.g. 1 Box of 1	0 Vials)	
preservative-free?		No				Product Sha	ipe:				Ampule					
correctional institution block?		Yes				Product Cold	or:	Green			Glass		Minimum o	rder quantity	/?	Yes
opioid?		No						0./00=			Tube					
Cannabinoid?	it dans for	No	Country of Origin	US		Product Impi	rint:	C / 335			Vial Liquid Sgl Vial Liquid Multi		If Voc. how	many of wh	ich package	turno?
If Unit Dose, is item bar coded to unhospital scanning?	unit dose for		Is this product covered u	nder the							Vial Powder Sql			Each	ich package	type r
If Unit Dose, indicate NDC here:			Trade Agreements Act (1		Yes						Vial Power Multi			Inner/Cartor	n/Pack	
											Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										-		
													-			
					Au	thorized Generic		horized Generic, other				ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating: AB				section	n fields are not applicable	ivec. sen unit to customer:				Rx billing unit to pharmacy:						
II. Generic Equivalent to What Bra	ınd?:	Cozaar®								oottle of 90	tablets		X	Each		
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION								(Write-in, e.g	. 1 Vial)				Gram Milliliter			
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION																
Does supplier meet DSCSA defini	ition of manufactu	irer?	Yes	7	GLN:	0359746000004					ITEM	AND PACKING I	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:									'		Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			iginal product pure	chased		Item/Each:		0.13	1.9	1.9	4	14.44	1
Is product sold by manufacturer's			No	-	direct from m			land dans dans	D/2 : -	·	20					
Has FDA granted waiver/exception If yes, attach documentation from		roduct?	No		Provide sour	ce manufacturer fo	or repack	kaged product	Box/Carton/E	Sundle/					0.00	
ii yes, attacii documentation noi	III I DA.								Case:							
		GTII	N AND HIBCC PRODUCT I	NFORMATION							7.95	15.5	11.75	5.25	956.16	48
									Pallet:						0.00	
Saleable Unit of Measure	5	Saleable Quantity	HIBCC			N-14	_	Unit of Use GTIN-14							0.00	
X Item/Each		1			003	59746335908				000	INFORMATION			MUOL FOAL	ER USE ONL	V.
Box/Carton/Bundle/Inner Pack X Case		48			403	59746335906				COS	HINFORWATION			WHOLESAL	ER USE UNL	.1.
A Case Pallet		40			403	33140333300	-		Regular Cost				Vendor #:			
									Invoice Cost			\$23.17	Whsl. Code	#:		
													Fineline Co	de:		
									As of date:				ļ			
1			Attach convet CAFETY DA	TA CUEET (00	C) or non-ba	rd lotter BACKACE	INICED	T LABEL AND DUOTO OF S	DECEMBER DACK	ACINC ac	I BABCODE					
	ormation on nage		Allacii copy of SAFETY DA	IIA SHEET (SD	or non naza) or non			T, LABEL AND PHOTO OF F	KUDUCI PACK	AGING and	DARCODE.					



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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?	SDS Hazard Classification						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?							
Is the product a CA Prop 65 carcinogen? No	Organic Corrosive Inorganic Oxidizer						
Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? No	Inorganic Oxidizer Steroid/Androgen Contact Hazard						
boes the product label bear a OATTOP to warning:	Ornaci Tazard						
c. Contact Hazard?	Does the product have an Aerosol class? If yes, No						
d. Does this product require special clean-up instructions?	identify NFPA Storage Level:						
(If yes, attach SDS with special instructions.)	NFPA Storage Level:						
e. Does the product contain DEHP?							
Is this product regulated for shipment by DOT?	Is the product a NIOSH hazardous drug?						
(if yes, answer a-e below and provide SDS)	If yes, indicate which:						
a. UN/Identification Number b. Proper Shipping Name							
c. DOT Hazard Class	Hazardous Waste Identification						
d. Packing Group							
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics						
Is this product regulated for shipment by IATA?							
(if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS						
a. UN/Identification Number							
b. Proper Shipping Name	Is there a REMS on this product?						
c. DOT Hazard Class d. Packing Group	If Yes, is it managed with a pharmacy registry? Website URL:						
e. Inhalation Hazard?	Website ORL.						
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? No	REMS:						
RQ Threshold:	REMS Program Manager Name: Phone:						
Is this a marine pollutant? No	Supplier Manages REMS registry exclusively:						
Is this product shipped utilizing an authorized DOT exception or Special Permit?	Wholesale distributor support:						
No (if yes, identify method below) Limited Quantity	Provider Name: DEA #: Site Enrollment Number assigned NCPDP#:						
Consumer Commodity, ORM-D	by Supplier: NPI #:						
Small Quantity (49 CFR 173.4)							
Special Permit; DOT-SP	Comments						
Special Provision (listed in Column 7 of 49 CFR 172.101);							
SP#	Registry:						
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone:						
	Comments						
Is the Product Controlled Substance 2	RETURN INSTRUCTIONS						
Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No	KETORI NOTIONS						
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:	Consider outletions or returns continued for this						
Restricted to hospital, clinics, and physician offices only:	Special regulations or returns requirements for this product in certain states?						
Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?						
Comments:							
MISCELLAN	IEOUS NOTES and/or Image of Product Barcode:						
- INIGCLELAT							



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FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop S	nip 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 Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	per:	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 Designa	ed Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order:		Overnight receipt available: PO Receipt cut off time:
Drop Ship miscellaneous fees billed: Comments:		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, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	s and physician offices	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to F	rocess 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?