

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

Version 2021						Introduction Type:	Post Launch Change		x Final Version			Date:	6/9/	2023
			PRODUCT INFORMA	TION					SPECIAL HAN	IDLING AND STO	RAGE 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	IDA/BLA (drug); P	MA/510(k)(med devic	:e):	2011	170				Temperature Range	Controlled Room		and 25 C (68	3° – 77° F)	
Medical Device Class, if applica	ble:							1						
DUNS:	022490515							-	Other Temperature Range	Requirement				
Proprietary Name (If Applicable)		ame: Losart	an Potassium Tablets					I	(write in)					
Selling Unit NDC:	59746-334-10		Unit of Use NDC:				9746-334-10-9		Notes					
UDI			CVX Code:			MVX Code:		1						
Description:	Losartan Potassi	um 50mg 1000ct Tabl	et					I	Is this product to be shippe	d to customers on	ice?		No	
									Is this product to be shippe	d to customers on	dry ice?		No	
Active Ingredient(s):		Losartan Potassium	1											
URL for Additional Product Inforr	nation:	www.cadista.com	m/products/full-produc	t-liet				b. Contact to	or temperature excursion qu Name:	estions:	Customer S	onvico		
Address:	207 Kiley Drive	www.cauista.coi	ni/products/ruir-produc	C IISC		Address 2:		†	Number:		(800) 313-46			
City:	Salisbury				State:		p: 21801	1	Group E-mail:			service@ca	adista.com	
Key Contact:	Customer Service	е			Email:	customer.service@	Ocadista.com							
Phone Number:	(800) 313-4623				Fax:	N/A		c. Special re	gulations for product in any				No	
Product Therapeutic Classification	on:	Antihypertensive							Special returns requiremen	ts for this product?			No	
								_						-
	ADDIT	IONAL PRODUCT IN	FORMATION			PRODUCT DESC	CRIPTION INFORMATION	d. Store prod	duct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship On	nly				Protect product (unit of sa	ale) from light?			No	
a legend device?		No	Is the Product	Neither		Size:	1000 count	e. Shelf life:					24	Months
if yes, enter class #		NI.	Orphan Drug Status				50mg		Initial shelf life at launch (if different):				Months
a product kit? if yes, list NDCs of		No	FDA Approval Status			Strength:	Soring			ORDER INFORI	MATION			
component parts			1 DA Approvar otatus				TABLETS			0113 <u>211 1111 0111</u>				
reverse numbered?		No				Dosage Form:			Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						X Bottle		1 bottle of 1	000 tablets		
latex-free?		Yes				Product Shape:	Oval, Scored		Box/Carton		(Write-in, e	.g. 1 Box of 1	0 Vials)	
preservative-free?		No					_		Ampule				_	
correctional institution block?		Yes				Product Color:	Green		Glass		Minimum o	rder quantity	/?	Yes
opioid? Cannabinoid?		No No	Country of Origin	US			C / 334		Tube Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for	INU	Country of Origin	00		Product Imprint:	C / 334		Vial Liquid Multi		If Yes how	many of whi	ich package	tyne?
hospital scanning?	unit dosc for		Is this product covered u	inder the					Vial Powder Sql			Each	ion paonago	.,,,,,,
If Unit Dose, indicate NDC here:			Trade Agreements Act (Yes				Vial Power Multi			Inner/Cartor	n/Pack	
				_					Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
					Au		Authorized Generic, other			HARMACY ORDER	R / BILL UNIT			
I. Orange Book Rating:	AB					Sec	tion fields are not applicable	_	t to customer?	-		nit to pharm	асу:	
II. Generic Equivalent to What Bra	and?:	Cozaar®							ottle of 1000 tablets		Х	Each		
		DRIIG SHIPPI	Y CHAIN SECURITY ACT (DSCSA) INFORM	MATION			(Write-in, e.g	j. 1 Viai)			Gram Milliliter		
		DRUG SUFFE	T CHAIN SECONTT ACT	(DSCSA) INI OKI	MATION							Ivillilitei		
Does supplier meet DSCSA defin	ition of manufactu	rer?	Yes	\neg	GLN:	0359746000004			ITEN	M AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			No											
If yes, select exemption:					GCP:	0359746		1		Dimens	ions (US msr	nts.)	Volume	Saleable #
Other exemption - Write in:									Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			iginal product purchase	ed	Item/Each:	0.41	2.4	2.4	5.08	29.26	1
Is product sold by manufacturer's			No	_	direct from m					2.4	2.7	0.00	25.20	
Has FDA granted waiver/exception		roduct?	No		Provide sour	ce manufacturer for rep	ackaged product	Box/Carton/l	Bundle/				0.00	
If yes, attach documentation fro	m FDA.							Inner Pack: Case:						
		GTI	N AND HIBCC PRODUCT I	NFORMATION				l Case.	7.87	10.25	7.75	8.25	655.36	12
		J						Pallet:						
Saleable Unit of Measure		Saleable Quantity	HIBCC		GTII	N-14	Unit of Use GTIN-14						0.00	
X Item/Each		1		_	003	59746334109								
Box/Carton/Bundle/Inner Pack									COST INFORMATION			WHOLESAL	ER USE ONL	Y:
X Case		12			403	59746334107								
Pallet								Regular Cos		6400.44	Vendor #:	ш.		
								Invoice Cost	(**************************************	\$189.11	Whsl. Code Fineline Co			
								As of date:						
											1			
	_							Ц						
1			Attach copy of SAFETY DA	ATA SHEET (SDS	s) or non haza	rd letter, PACKAGE INSI	ERT, LABEL AND PHOTO OF F	PRODUCT PACK						
*Please provide any additional in							gnated Drop Ship Only.		Signature:					



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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?