

# **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	HANDLING AND STO	RAGE REQU	IREMENTS*		
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/510(k)(med device): 201845						<u> </u>		Temperature Range	Controlled Room			3° – 77° F)		
Medical Device Class, if applicable:														
DUNS:	022490515							_	Other Temperature Ra	nge Requirement				
Proprietary Name (If Applicable) a		ame: Losar	tan - HCTZ Tablets					I	(write in)					
Selling Unit NDC:	59746-339-90		Unit of Use NDC:				59746-339-90-6		Notes					
UDI			CVX Code:			MVX Code:		1						
Description:	Description: Losartan Potassium - Hydrochlorothiazide 100-25mg 90ct Tablet Is this product to be shipped to customers on ice? No													
Is this product to be shipped to customers on dry ice?									No					
Active Ingredient(s): Losartan Potassium; Hydrochlorothiazide														
									or temperature excursio Name:	questions:	Customer S	`a=:!a=		
Address:	207 Kiley Drive	www.cauista.co	in/products/run-produc	t-list		Address 2:		+	Number:		(800) 313-4			
City:	Salisbury				State:		ip: 21801	1	Group E-mail:			.service@ca	ndista com	
Key Contact:	Customer Service	9			Email:	customer.service		1			<u>oustorner</u>	isci vicce co	- Constance - Cons	
Phone Number:	(800) 313-4623				Fax:	N/A		c. Special re	gulations for product in	any states?			No	1
Product Therapeutic Classification	on:	Antihypertensive						_	Special returns require	ments for this product?	•		No	
	ADDIT	IONAL PRODUCT IN	FORMATION			PRODUCT DES	CRIPTION INFORMATION	d. Store pro	duct (unit of sale) uprigh	t?			No	
The product is?			Is the Product	Direct-Ship Or	nly				Protect product (unit	of sale) from light?			No	1
a legend device?		No	Is the Product	Neither		Size:	90 count	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status			Size.			Initial shelf life at laur	ch (if different):				Months
a product kit?		No				Strength:	100mg-25mg							
if yes, list NDCs of			FDA Approval Status				T.D. 5TO			ORDER INFOR	MATION			
component parts reverse numbered?		NI.				Dosage Form:	TABLETS		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No No	Allergens Present						X Bottle		1 bottle of 9		uiiit:	
latex-free?		Yes	Allergens i resent				Oval		Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		No				Product Shape:			Ampule		(			
correctional institution block?		Yes				Product Color:	Yellow		Glass		Minimum o	order quantity	1?	Yes
opioid?		No				Froduct Color.			Tube					
Cannabinoid?		No	Country of Origin	US		Product Imprint:	C / 339		Vial Liquid So					
If Unit Dose, is item bar coded to	unit dose for								Vial Liquid M			many of wh	ich package	type?
hospital scanning? If Unit Dose, indicate NDC here:			Is this product covered under the Agreements Act (		Yes				Vial Powder S Vial Power M		24	Each Inner/Cartor	/Deels	
Il Offit Dose, indicate NDC fiere.			Trade Agreements Act (	174):	162				Other: Write			Case	I/FdUK	
			FOR GENERIC DRUG PR	ODUCTS				1		•				
					Au	thorized Generic *If	Authorized Generic, other			PHARMACY ORDER	R / BILL UNIT			
I. Orange Book Rating:	AB					se	ction fields are not applicable	Rec. sell uni	t to customer?		Rx billing ı	unit to pharm	acv:	
II. Generic Equivalent to What Bra	and?:	Hyzaar		_				1	bottle of 90 tablets		х	Each	,	
								(Write-in, e.g	g. 1 Vial)			Gram		
		DRUG SUPPI	LY CHAIN SECURITY ACT (	(DSCSA) INFORI	MATION							Milliliter		
Does supplier meet DSCSA defin		2	Yes	_	GLN:	0359746000004				TEM AND PACKING	INFORMATIO	M		
Is product exempt from DSCSA?	ition of manufactu	rer?	No	_	GLN:	0359746000004				TEM AND FACKING	INFORMATIC	/N		
			***		000	0050740		1		D:	ione (IIC	mto \	37-1	0-1
If yes, select exemption: Other exemption - Write in:					GCP:	0359746		1	Weight Lb	s. Depth	sions (US ms Width	mts.) Height	Volume (Cube)	Saleable # Pieces
Is product repackaged?			No		lf ves was or	iginal product purcha	ed	Item/Each:		1			·	
Is product sold by manufacturer's	s exclusive distrib	utor?	No		direct from m		seu	item/Lucii.	0.18	1.9	1.9	4	14.44	1
Has FDA granted waiver/exception			No		Provide source	ce manufacturer for re	packaged product	Box/Carton/	Bundle/				0.00	
If yes, attach documentation fro	m FDA.							Inner Pack:					0.00	
								Case:	5.07	11.75	8	5.25	493.50	24
		GT	IN AND HIBCC PRODUCT I	NFORMATION					***					
Saleable Unit of Measure	,	and the contract of	LUDOO		OTI		Helt of Helt OTIN 44	Pallet:					0.00	
X Item/Each		Saleable Quantity	HIBCC			N-14 59746339906	Unit of Use GTIN-14							
Box/Carton/Bundle/Inner Pack		-			003	331 40333300			COST INFORMAT	ON		WHOLESAL	ER USE ONL	-Y:
X Case		24			403	59746339904								
Pallet					. 50			Regular Cos	t		Vendor #:			
								Invoice Cos	(WAC) (\$)	\$26.10	Whsl. Code	e #:		
											Fineline Co	ode:		
								As of date:						
1			Attach copy of SAECTY D	ATA QUEET (CDG	ar non he	rd latter DACKACE INC	SERT, LABEL AND PHOTO OF F	DECEMBER DACK	ACINC and PARCORE		<u> </u>			
*Please provide any additional in	formation on nage	2	Audul copy of SAFETY DA	AIA SHEET (SUS	o, or non naza		signated Drop Ship Only.	RODUCI PACK	Signature:					
	page					p. o ioi Dei								



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#### Version 2021

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	- Hazardolo Habit Identification						
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							



## **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 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?