

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

Version 2021						Introduction T	ype:	Post Launch Change		x F	inal Version			Date:	6/9/2	2023
PRODUCT INFORMATION							SPECIAL HANDLING AND STORAGE REQUIREMENTS					REMENTS*				
Company Name: Jubilant Cadista Pharmaceuticals Inc. Application: ANDA							a. Temperature – Indicate the USP temperature range for this product.									
Application Number for NDA/AN				201	845					Temperatu		Controlled Room		and 25 C (68	3° – 77° F)	
Medical Device Class, if applica																
DUNS:	022490515										perature Range F	Requirement				
Proprietary Name (If Applicable) a		ame: Losa	artan - HCTZ Tablets		1	UPC:				(write	in)					
Selling Unit NDC: UDI	59746-339-10		Unit of Use NDC: CVX Code:			MVX Code:	3-59746-33	9-10-4	+	Notes						
						IN VX Gode.			1							1
Description:	Losartan Potassii	um - Hydrochlorothia	azide 100-25mg 1000ct Tablet									to customers on i to customers on o			No No	
Active Ingredient(s):		Losartan Potassiu	um; Hydrochlorothiazide						†	is tills proc	idet to be shipped	1 to customers on t	ary ice:		140	1
b. Contact for temperature excursion questions:																
URL for Additional Product Inform		www.cadista.c	om/products/full-product	<u>-list</u>						Name:			Customer S			
Address:	207 Kiley Drive				.	Address 2:				Number:			(800) 313-46			
City: Key Contact:	Salisbury Customer Service				State: Email:	MD Zip: 21801 customer.service@cadista.com			Group E-mail:				customer.service@cadista.com			
Phone Number:	(800) 313-4623				Fax:	N/A	<u>ce@cauist</u>	.d.COIII	c. Special regulations for product in any states? Special returns requirements for this product?						No	1
Product Therapeutic Classification		Antihypertensive				14/1							No			
Special returns requirements for this product: NO																
	ADDITI	IONAL PRODUCT I	INFORMATION			PRODUCT D	DESCRIPTION	ON INFORMATION	d. Store prod	duct (unit of	sale) upright?				No	1
The product is?			Is the Product	Direct-Ship O	nly					Protect pr	oduct (unit of sa	le) from light?			No	1
a legend device?		No	Is the Product	Neither		Size:	100	0 count	e. Shelf life:	•	•	, ,			24	Months
if yes, enter class #			Orphan Drug Status			Size.				Initial she	f life at launch (if different):				Months
a product kit?		No	FDA 4			Strength:	Strength: 100mg-25mg					ORDER INFORM	MATION			
if yes, list NDCs of component parts			FDA Approval Status				TAR	LETS				ORDER INFORM	HATION			
reverse numbered?		No				Dosage Form	n:	LL 13		Unit of Sa	le		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present								lottle		1 bottle of 1	000 tablets		
latex-free?		Yes				Product Shap	ova	I			lox/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		No									mpule				_	
correctional institution block? opioid?		Yes No				Product Colo	Yell	DW			lass ube		Minimum o	rder quantity	/?	Yes
Cannabinoid?		No	Country of Origin	US			. C/3	339			ial Liquid Sql					
If Unit Dose, is item bar coded to	unit dose for		,g			Product Impr	rint:				'ial Liquid Multi		If Yes, how	many of wh	ich package	type?
hospital scanning?			Is this product covered u								ial Powder Sql			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (T	AA)?	Yes						ial Power Multi			Inner/Cartor	n/Pack	
									<u>l</u>		Other: Write In			Case		
			FOR GENERIC DRUG PRO	DDUCTS												
					Au	thorized Generic	*If Authoriz	ed Generic, other			PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	acetics fields are not applied					Rec. sell unit to customer? Rx billing unit to pharmacy:										
II. Generic Equivalent to What Bra		Hyzaar®								ottle of 1000		1	X	Each	uo,.	
							(Write-in, e.g. 1 Vial)			Gram						
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION								Milliliter								
Does supplier meet DSCSA defini	ition of monufactu	ror2	Yes	7	GLN:	0359746000004					ITEN	I AND PACKING I	NEORMATIO	N		
Is product exempt from DSCSA?	o or manaractu		No		J_11.	55507 4000004										
If yes, select exemption:					GCP:	0359746			i			Dimensi	ions (US msr	nts.)	Volume	Saleable #
Other exemption - Write in:									1		Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			riginal product purc	hased		Item/Each:		1.27	3.5	3.5	6.4	78.40	1
Is product sold by manufacturer's			No	1	direct from m						,	3.0	3.0	5.4	. 5.40	,
Has FDA granted waiver/exception If yes, attach documentation from		roduct?	No		Provide sour	ce manufacturer for	r repackage	ed product	Box/Carton/E	Bundle/					0.00	
ir yes, attach documentation fro	m FDA.								Case:							
		G.	TIN AND HIBCC PRODUCT IN	IFORMATION							18.22	14.25	10.75	8	1225.50	12
									Pallet:						0.00	
Saleable Unit of Measure	\$	Saleable Quantity	HIBCC			N-14	Un	it of Use GTIN-14							0.00	
X Item/Each		1			003	59746339104				COST	INFORMATION			WHOLESAL	ER USE ONL	V
Box/Carton/Bundle/Inner Pack X Case		12			403	59746339102	-			- 6031	INTORWATION			WHOLESAL	EK USE UNL	.1.
Pallet					-03	11. 10000102	1		Regular Cos	t			Vendor #:			
]		Invoice Cost			\$290.00	Whsl. Code			
										_			Fineline Co	de:		
							-		As of date:				-			
									11				1			
							-		11							
1			Attach copy of SAFETY DA	TA SHEFT (SD	S) or non haza	rd letter, PACKAGE	INSERT 1.4	ABEL AND PHOTO OF F	PRODUCT PACK	AGING and I	BARCODE		ļ			



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

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								
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?