

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

Version 2021						Introduction T	ype:	Post Launch Change]	x Fir	nal 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				201	845					Temperature		Controlled Room		and 25 C (68	3° – 77° F)		
Medical Device Class, if applica																	
DUNS:	022490515								7		erature Range F	Requirement					
Proprietary Name (If Applicable) a		ame: Losa	artan - HCTZ Tablets		1	uno			-	(write i	in)						
Selling Unit NDC: UDI	59746-338-30		Unit of Use NDC: CVX Code:			UPC: MVX Code:	3-59746-33	8-30-5	+	Notes							
						III V X OOUC.			1							1	
Description:	Losartan Potassi	um - Hydrochlorothia	azide 100-12.5mg 30ct Tablet									d to customers on i			No No		
Active Ingredient(s):		Losartan Potassii	um; Hydrochlorothiazide						†	is this produ	ict to be shipped	1 to customers on	ny 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 Service				
Address:	207 Kiley Drive					Address 2:				Number:			(800) 313-4				
City:	Salisbury Customer Service				State: Email:	MD customer.servi	Zip : 21		Group E-mail:			customer.service@cadista.com					
Key Contact: Phone Number:	(800) 313-4623				Fax:	N/A	ice@cadisi	.a.com	c. Special regulations for product in any states?				Nr		No	_	
Product Therapeutic Classification		Antihypertensive				IVA			o. opeciai re	-			No				
Product Therapeutic Classification: Antihypertensive Special returns requirements for this product? No									J								
	ADDIT	IONAL PRODUCT I	INFORMATION			PRODUCT D	DESCRIPTION	ON INFORMATION	d. Store prod	duct (unit of s	ale) upright?				No	1	
The product is?			Is the Product	Direct-Ship O	nlv				11	-		ale) from light?			No	i	
a legend device?		No	Is the Product	Neither		Size:	30 c	count	e. Shelf life:	otoot p. o	auot (aint oi oc	,g			24	Months	
if yes, enter class #			Orphan Drug Status			Size:				Initial shelf	life at launch (if different):				Months	
a product kit?		No				Strength: 100mg-12.5mg							·				
if yes, list NDCs of			FDA Approval Status				TAR	SLETS				ORDER INFOR	MATION				
component parts reverse numbered?		No				Dosage Form	n:	SLETS		Unit of Sale			What is the	NDC selling	unit?		
co-licensed?		No	Allergens Present							X Bo			1 bottle of 3				
latex-free?		Yes				Product Shap	Ova	I		Во	x/Carton		(Write-in, e	.g. 1 Box of 1	0 Vials)		
preservative-free?		No				Froduct Snap					npule						
correctional institution block?		Yes				Product Colo	or: Whi	te			ass		Minimum o	rder quantity	y?	Yes	
opioid? Cannabinoid?		No No	Country of Origin	US			C/:	220			ibe al Liquid Sql						
If Unit Dose, is item bar coded to u	unit dose for	INO	Country of Origin	03		Product Impr	rint:	550			al Liquid Sgi al Liquid Multi		If Yes, how	many of wh	ich package	type?	
hospital scanning?	unit dosc for		Is this product covered up	nder the							al Powder Sql			Each	ion paonago	., p	
If Unit Dose, indicate NDC here:			Trade Agreements Act (T		Yes						al Power Multi			Inner/Cartor	n/Pack		
]	Ot	her: Write In			Case			
			FOR GENERIC DRUG PRO	DDUCTS													
							#16 A calls a size	and Community authors			DU	IADMACY ORDER	/ DILL LINIT				
				_	Au	thorized Generic		ed Generic, other ds are not applicable	PHARMACY ORDER / BILL UNIT								
I. Orange Book Rating: II. Generic Equivalent to What Bra	AB	Hyzaar				Section fields are not applicable				Rec. sell unit to customer? 1 bottle of 30 tablets				Rx billing unit to pharmacy: X Each			
II. Generic Equivalent to what Bra	ana?:	пугааг							(Write-in, e.g		DIETS		_ X	Gram			
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMAT				MATION					, v.a.,				Milliliter				
Does supplier meet DSCSA defini	ition of manufactu	irer?	Yes		GLN:	0359746000004					ITEN	I AND PACKING I	NFORMATIO	N			
Is product exempt from DSCSA?			No														
If yes, select exemption:					GCP:	0359746]		Weight Lbs.		ons (US msi	•	Volume	Saleable #	
Other exemption - Write in: Is product repackaged?			No		K				Item/Each:			Depth	Width	Height	(Cube)	Pieces	
Is product repackaged?	s avelusiva distrib	utor?	No	-	direct from m	riginal product purd	cnased		item/Each:		0.11	1.9	1.9	4	14.44	1	
Has FDA granted waiver/exception			No	+		 ce manufacturer fo	r repackage	ed product	Box/Carton/E	Bundle/					0.00		
If yes, attach documentation fro								·	Inner Pack:						0.00		
									Case:		3.15	11.75	8	5.25	493.50	24	
		G'	TIN AND HIBCC PRODUCT IN	IFORMATION								-					
Saleable Unit of Measure		Saleable Quantity	HIBCC		CTI	N-14	He	it of Use GTIN-14	Pallet:						0.00		
X Item/Each	,	Saleable Quantity	ПВСС			59746338305	UI	III OF USE GTIN-14									
Box/Carton/Bundle/Inner Pack							COST INFORMATION V					WHOLESAL	VHOLESALER USE ONLY:				
X Case		24			403	59746338303											
Pallet	_								Regular Cost				Vendor #:				
									Invoice Cost	(WAC) (\$)		\$8.54	Whsl. Code				
							-		As of date:				Fineline Co	ae:			
									As of date:				1				
							a de la companya de		11								
			Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza	rd letter, PACKAGE	INSERT, LA	ABEL AND PHOTO OF F	PRODUCT PACK	AGING and B	ARCODE.		<u> </u>				



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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?