

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

						Introduction Type	e: Post Launch Change		x Final Version			Date:	7/12/	2021
			PRODUCT INFORMAT	TION					SPECIAL HAND	LING AND STOR	AGE REQUI	REMENTS*		
Company Name:	Juhilant Cadista F	harmaceuticals Inc.				Applicatio	n: ANDA	a Temperature -	- Indicate the USP temper	rature range for th	his product			
Application Number for NDA/AN			·e)·	20	1845	7.ppout.o	/ /			Controlled Room -		and 25 C (68	3° – 77° F)	
Medical Device Class, if applical		iii uu ru(ii)(iiiuu uu iii		<u> </u>				· ·	inporataro rtango					
DUNS:	022490515				T T				ther Temperature Range R	equirement				
Proprietary Name (If Applicable) a		me: Losarta	an - HCTZ Tablets						(write in)					
Selling Unit NDC:	59746-337-10		Unit of Use NDC:			UPC: 3	-59746-337-10-0	- N	otes					
UDI			CVX Code:			MVX Code:								
Description:	Locartan Potaccii	ım - Hydrochlorothiaz	ide 50-12.5mg 1000ct Table					- Io	this product to be shipped	to quotomoro on i	202		No	
Description.	Losartari i otassit	iiii - i iyalociilolotiilaz	de 30-12.3mg 1000ct Table	·L					this product to be shipped				No	
Active Ingredient(s):		Losartan Potassium	; Hydrochlorothiazide					-	and product to be shipped	to customers on a	ny ioo:		140	
riouro iligi ouloni(o).			,,					b. Contact for te	mperature excursion que	stions:				
URL for Additional Product Inform	mation:	www.cadista.com	m/products/full-product	t-list					ame:		Customer Se	ervice		
Address:	207 Kiley Drive					Address 2:		N	umber:		(800) 313-46	23		
City:	Salisbury	Sta			State:	MD	Zip : 21801	G	Group E-mail: customer.service@cadista.c			dista.com		
Key Contact:	Jackie Emershaw				Email:	Jackie.Emershav	<u>/@jubl.com</u>							
Phone Number:	(410) 912-3722				Fax:	(215) - 443 - 9646		c. Special regula	ations for product in any s	states?			No	
Product Therapeutic Classificatio	on:	Antihypertensive						Si	pecial returns requirements	for this product?			No	
					_									
	ADDITI	ONAL PRODUCT INF	ORMATION			PRODUCT DE	SCRIPTION INFORMATION	d. Store product	(unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship (Only			Pi	rotect product (unit of sal	e) from light?			No	
a legend device?		No	Is the Product	Neither			1000 count	e. Shelf life:		,			24	Months
if yes, enter class #		1.14	Orphan Drug Status			Size:		In	itial shelf life at launch (if	different):				Months
a product kit?		No	. •			Ctuo month.	50mg-12.5mg		,	•				
if yes, list NDCs of			FDA Approval Status			Strength:				ORDER INFORM	IATION			
component parts						Dosage Form:	TABLETS							
reverse numbered?		No				Dosage Form.		U	nit of Sale		What is the		unit?	
co-licensed?		No	Allergens Present						X Bottle		1 bottle of 10			
latex-free?		Yes				Product Shape	Oval		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		No							Ampule				_	
correctional institution block?		Yes				Product Color:	Yellow	_	Glass		Minimum o	der quantity	?	Yes
opioid? Cannabinoid?		No	0	US			0.4007	_	Tube					
		No	Country of Origin	05		Product Imprir	t: C / 337	-	Vial Liquid Sgl		K Vaa haw		iah maakama	4
If Unit Dose, is item bar coded to unhospital scanning?	unit dose for		Is this product covered u	andor the				-	Vial Liquid Multi Vial Powder Sql			many or wni Each	ich package t	type?
If Unit Dose, indicate NDC here:			Trade Agreements Act (1	TAA1?	Yes				Vial Power Multi		12	Inner/Carton	/Dook	
Il Ollit Dose, Ilidicate NDC liele.					162				Other: Write In			Case	/Fack	
			EOR GENERIC DRUG PRO	ODUCTS		-		╝	Other: write in			Case		
			FOR GENERIC DRUG PRO	ODUCTS		<u> </u>			Other: Write in			Case		
			FOR GENERIC DRUG PRO	ODUCTS	Δυ	uthorized Generic *	If Authorized Generic, other			ARMACY ORDER	/ BILL UNIT	Case		
L Course Paul Patien	IAD.		FOR GENERIC DRUG PRO	ODUCTS	Au		If Authorized Generic, other ection fields are not applicable	Pag adli unit to	PH.	ARMACY ORDER				
I. Orange Book Rating:	AB	Ularea	FOR GENERIC DRUG PRO	ODUCTS	Au		If Authorized Generic, other ection fields are not applicable	Rec. sell unit to	PHAcustomer?	ARMACY ORDER	Rx billing u	nit to pharm	зсу:	
I. Orange Book Rating: II. Generic Equivalent to What Bra		Hyzaar	FOR GENERIC DRUG PR	ODUCTS	Au			1 bottle	PHAcustomer?	ARMACY ORDER		nit to pharm	acy:	
								_	PHAcustomer?	ARMACY ORDER	Rx billing u	nit to pharm Each Gram	асу:	
			FOR GENERIC DRUG PRO					1 bottle	PHAcustomer?	IRMACY ORDER	Rx billing u	nit to pharm	acy:	
	and?:	DRUG SUPPL						1 bottle	PHACustomer? of 1000 tablets //ial)	IRMACY ORDER	Rx billing u	nit to pharma Each Gram Milliliter	acy:	
II. Generic Equivalent to What Bra	and?:	DRUG SUPPL	Y CHAIN SECURITY ACT (RMATION	s		1 bottle	PHACustomer? of 1000 tablets //ial)		Rx billing u	nit to pharma Each Gram Milliliter	acy:	
II. Generic Equivalent to What Bra Does supplier meet DSCSA defini Is product exempt from DSCSA?	and?:	DRUG SUPPL	Y CHAIN SECURITY ACT (I		RMATION GLN:	0359746000004		1 bottle	PHA customer? of 1000 tablets //al)	AND PACKING IN	Rx billing u X	nit to pharm. Each Gram Milliliter		Salashia #
II. Generic Equivalent to What Bra Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption:	and?:	DRUG SUPPL	Y CHAIN SECURITY ACT (I		RMATION	s		1 bottle	PHACustomer? of 1000 tablets //ial)	AND PACKING IN	Rx billing under X NFORMATION Ons (US msn	nit to pharm Each Gram Milliliter	Volume	Saleable #
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II. Generic Equivalent to What Bra Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	and?: ition of manufacture s exclusive distribu	DRUG SUPPL	Y CHAIN SECURITY ACT (I Yes No		GLN: GCP: If yes, was or purchased di	0359746000004 0359746 riginal product irect from mfr?	ection fields are not applicable	1 bottle (Write-in, e.g. 1 \	PHA customer? of 1000 tablets //ial) ITEM Weight Lbs. 0.67	AND PACKING IN Dimensio Depth	Rx billing u X NFORMATION ons (US msm Width	nit to pharm. Each Gram Milliliter	Volume (Cube)	Pieces
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Version 2021

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



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Version 2021

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

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing					
Purchase orders may be accepted by: a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	Purchase order daily receipt cut off time by supplier Cut off time: 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 Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing					
Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday					
Class of Trade Restriction: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments: Other Data Information Required to Process PO:	Priority Overnight receipt available: PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply: Return Instructions					
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty: Miscellaneous Notes:	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?					
	ADDITIONAL INFORMATION Is product order for scheduled patient procedure? Is product order for restocking purposes?					