

Standard Pharmaceutical Product Information (Rx Product Only)

					Introducti	on type.	Post Launch Change		x Final Version			Date:	4/14	
			PRODUCT INFORMATION						SPECIAL HANDL	ING AND ST	ORAGE REQ	UIREMENTS	*	
Company Name:	Jubilant Cadista Phar	rmaceuticals Inc.				Application:	ANDA	a. Temperature – I	ndicate the USP temper	rature range	for this prod	ıct.		
			201170	01170				perature Range				en 20 and 25	C (68° - 77° I	
DUNS:	022490515							Othe	er Temperature Range R	equirement				
Proprietary Name (If Applica		Name: Losartan						11	(write in)					1
Selling Unit NDC:	59746-0334-10		Individual Unit NDC:		UP	C: 3-59746-334	410-9							_
UDI		•	CVX Code:	•	MVX Code	e:		Is th	is product to be shipped	to customers	on ice?		No	-
Description:	Description: Losartan 50mg Tablet 1000							Is this product to be shipped to customers on dry ice?						
Active Ingredient(s): Losartan Potassium						b. Contact for temperature excursion questions:								
								Name:			Customer Service			
URL for Additional Product I Address:					Address 2:			Number: Group E-mail:			(800) 313-4623			
City:	207 Kiley Drive			State	Address 2:			Grou	up E-maii:					
Key Contact:	Salisbury Jackie Emershaw				Email: Jackie.Emershaw@cadista.com			c. Special regulation	ons for product in any	states?			No	
Phone Number:	(410) 912-3722			Fax:					cial returns requirements		uct?		No	-
Product Therapeutic Classifi	ication:	Antihypertensive						1	•	•				•
								d. Store product (u	unit of sale) upright?				No	
ADDITIONA	AL PRODUCT INFORM	MATION			PRODUCT DESC	RIPTION INFOR	MATION	Prot	tect product (unit of sal	e) from light?	?		No	-
Is the Product								e. Shelf life:					24	Months
a legend device?		Yes			Size: 1000			Initia	al shelf life at launch (if	different):	Mont		Months	
reverse numbered?			No		Size.									
co-licensed? Is the Product		No No		Strength:	50mg					ORDER INFO	RMATION			
Is the Product		Direct-Ship Only							t of Sale		What is the	NDC selling	unit?	
is the Froudet				Dosage For	m: Table	ts			x Bottle		1 case of 12			
If Unit Dose, is item bar code		o de la casa de la cas							Box/Carton			g. 1 Box of 1	0 Vials)	
· ·	·	oliai scanning?		Product Sha	ape: Oval				Ampule					
If Unit Dose NDC, indicate N	IDC here:				Troduct onape.			Glass		Minimum o	rder quantity	?	Yes	
Country of Origin				Product Col	or: Green	1			Tube Vial Liquid Sgl					
								II -	Vial Liquid Sgi		If Yes, how	many of wh	ich package	type?
Is this product covered under	r the Trade Agreement	s Act (TAA)? Yes		Product Imp	Product Imprint: C' / '334'				Vial Powder Sql			Each	pg-	-71
								 - 				Inner/Carton	/Dook	
									Vial Power Multi			IIIIIei/Cartor	/Fack	
			FOR OFNERIO PRINC PROPIN	270				<u> </u>	Other: Write In	_		Case	/FdCK	
			FOR GENERIC DRUG PRODUC	CTS				<u>'</u>					/FdCK	
			FOR GENERIC DRUG PRODUC		thorized Generic	*If Authorize	ed Generic, other section		Other: Write In	RMACY ORDI	ER / BILL UN	Case	/Fduk	
I. Orange Book Rating:	АВ		FOR GENERIC DRUG PRODUC		thorized Generic	*If Authorize fields are no	ed Generic, other section ot applicable	Rec. sell unit to cu	Other: Write In	RMACY ORD		Case		
I. Orange Book Rating:	AB at Brand?:	Cozaar®	FOR GENERIC DRUG PRODUC		thorized Generic			Rec. sell unit to cu	Other: Write In	RMACY ORD		Case		
		Cozaar®		Aut	thorized Generic			Rec. sell unit to cu	Other: Write In PHAF ustomer?	RMACY ORD		Case T nit to pharm Each Gram		
		Cozaar®	FOR GENERIC DRUG PRODUC	Aut	thorized Generic				Other: Write In PHAF ustomer?	RMACY ORD		Case T nit to pharm Each		
II. Generic Equivalent to Wha	at Brand?:	Cozaar® DRUG SUPPLY	CHAIN SECURITY ACT (DSC	Aut GA) INFORMATION		fields are no			Other: Write In PHAF istomer?		Rx billing u	Case T nit to pharm Each Gram Milliliter		
II. Generic Equivalent to What Does supplier meet DSCSA	at Brand?: definition of manufact	Cozaar® DRUG SUPPLY turer?		Aut	035974600000	fields are no			Other: Write In PHAF istomer?	RMACY ORDI	Rx billing u	Case T nit to pharm Each Gram Milliliter		
II. Generic Equivalent to Wha	at Brand?: definition of manufact	Cozaar® DRUG SUPPLY turer?	CHAIN SECURITY ACT (DSCS	Aut GA) INFORMATION		fields are no			Other: Write In PHAF istomer? ITEM A	AND PACKING	Rx billing u	Case T nit to pharm Each Gram Milliliter		# Biococc
II. Generic Equivalent to What Does supplier meet DSCSA Is product exempt from DSC If yes, select exemption: Other exemption - Write in:	at Brand?: definition of manufact	DRUG SUPPLY turer?	/ CHAIN SECURITY ACT (DSCS Yes	Aut SA) INFORMATION GLN:	035974600000	fields are no		(Write-in, e.g. 1 Via	Other: Write In PHAF istomer?	AND PACKING	Rx billing u	Case T nit to pharm Each Gram Milliliter	acy:	#Pieces:
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Does supplier meet DSCSA is product exempt from DSC if yes, select exemption: Other exemption - Write in: is product repackaged? Is product sold by manufact	at Brand?: definition of manufact SA? urer's exclusive distri	DRUG SUPPLY turer?	Y CHAIN SECURITY ACT (DSCS	Automation GLN: If Yes, was origing from mfr?	035974600000	fields are no		(Write-in, e.g. 1 Via	Other: Write In PHAF ustomer? ITEM A Weight Lbs. 0.41	ND PACKING Dime Depth	Rx billing u S INFORMAT nsions (US n Height	Case IT nit to pharm Each Gram Milliliter ION msmts.) Width	volume (Cube)	
II. Generic Equivalent to What Does supplier meet DSCSA is product exempt from DSC if yes, select exemption: Other exemption - Write in: Is product repackaged?	at Brand?: definition of manufact SA? urer's exclusive distri	DRUG SUPPLY turer?	Yes No	Automation GLN: If Yes, was origing from mfr?	035974600000	fields are no		(Write-in, e.g. 1 Via	Other: Write In PHAF ustomer? ITEM A Weight Lbs. 0.41	ND PACKING Dime Depth	Rx billing u S INFORMAT nsions (US n Height	Case IT nit to pharm Each Gram Milliliter ION msmts.) Width	volume (Cube)	
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Does supplier meet DSCSA Is product exempt from DSC If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufact Has FDA granted waiver/exc	at Brand?: definition of manufact SA? . urer's exclusive distri ception/exemption for	DRUG SUPPLY turer?	Yes No No No No STIN PRODUCT INFORMATIC Level Un Item Box/Cartor/Bundle/Inner Pack	If Yes, was origing from mfr? If yes, attach do	035974600000 inal product purcipocumentation from	hased direct n FDA. Quantity	GTIN-14 00359746334109	(Write-in, e.g. 1 Via	Other: Write In PHAF Istomer? ITEM A Weight Lbs. 0.41 7.77 Case:	Dime Depth 2.4	S INFORMAT nsions (US n Height 4.75	Case IT nit to pharm Each Gram Milliliter ON nsmts.) Width 2.4	Volume (Cube) 27.36 0	1
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Does supplier meet DSCSA Is product exempt from DSC If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufact Has FDA granted waiver/exc	at Brand?: definition of manufact SA? . urer's exclusive distri ception/exemption for	DRUG SUPPLY turer? 1	Yes No No No No STIN PRODUCT INFORMATIC Level Un lem Box/Carton/Bundle/Inner Pack Case X	If Yes, was origing from mfr? If yes, attach do 20	035974600000 inal product purciporation from Linear Linea	hased direct n FDA. Quantity 1 12	GTIN-14 00359746334109 40359746334107	(Write-in, e.g. 1 Via Item: Box/Carton/Bundle Inner Pack: Case: Pallet: UPC: Regular Cost Invoice Cost (WAC Federal Excise Tax As of date:	Other: Write In PHAI ISTOMER? All) ITEM A Weight Lbs. 0.41 6/ 7.77 Case: Carton: OST INFORMATION C) (\$) X Per Unit of Sale	Dime Depth 2.4	Rx billing u S INFORMAT Rsions (US n Height 4.75 8.25 Vendor #:	Case IT nit to pharm Each Gram Milliliter NION ISSMED. Width 2.4 7.75	Volume (Cube) 27.36 0 655.36	1 12



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): SDS Hazard Classification a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? No Inorganic Oxidizer Does the product label bear a CA Prop 65 warning? No Steroid/Androgen Contact Hazard c. Contact Hazard? No Aerosol Class; Identify NFPA Storage Level: d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) Is the product a NIOSH hazardous drug? e. Does the product contain DEHP? No If yes, indicate which: Is this product regulated for shipment by DOT or IATA? No (if yes, answer a-e below and provide SDS) a. UN/Identification Number Hazardous Waste Identification b. Proper Shipping Name c. DOT Hazard Class EPA Hazardous Waste Code: d. Packing Group No e. Inhalation Hazard? REMS or REGISTRY RESTRICTIONS Is the product restricted for air shipment? If so, indicate restriction: Passenger Is there a REMS on this product? Cargo If Yes, is it managed with a pharmacy registry? Passenger & Cargo Website URL: Is this a reportable quantity? No RQ Threshold: Comments / Details: (For example, iPledge program?) Is this a marine pollutant? Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below) REMS Program Manager Name: Limited Quantity Phone: Consumer Commodity, ORM-D Supplier Manages REMS registry exclusively: Small Quantity (49 CFR 173.4) Wholesale distributor support: Special Permit: DOT-SP Provider Name: Special Provision (listed in Column 7 of 49 CFR 172.101); Site Enrollment Number assigned DEA #: by Supplier: SP# PCPDP #: NPI#: ADD'L STORAGE INFORMATION Is the Product... Comments Controlled Substance? No Controlled by State(s)? No Registry: ARCOS Reportable? No Registry Program Contact Name: Schedule No. (inc. N for non-narcotic) Comments Controlled Substance Code Listed Chemical (List I or II) No RETURN INSTRUCTIONS If yes, indicate which: Is it a scheduled listed chemical product?: No (410) 912 - 3722 Contact tel. # if product received damaged: CLASS OF TRADE RESTRICTION: Yes Is product returnable for credit: Yes www.cadista.com No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices URL/Link to returns policy: Restricted to retail pharmacy only: No Special regulations or returns requirements for this product in certain states? Restricted to hospital, clinics, and physician offices only: No If so, which states? Other requirements? Comments? Restricted from US territories? (explain in comments) No Comments: MISCELLANEOUS NOTES and/or Image of Product Barcode:



Standard Pharmaceutical Product Information (Page 3)

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:	Purchase order daily receipt cut off time by supplier					
a. EDI Yes	Cut off time:					
b. Autofax Yes Fax Number:						
c. Fax Yes Fax Number:	Shipping lead time of PO: Hours Days					
d. Phone only						
e. Supplier Web Site only Site Address:	Ships same day for next day receipt:					
Minimum Order Quantity: 12	Ships for second day receipt:					
Supplier's Customer Service Number: (410) 912 - 3722	Ships regular ground for 3-10 days receipt:					
Contracted 3PL company / contact #: Name:						
Phone:						
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing					
Expedited freight fees billed with each order:	Overnight receipt available:					
Drop Ship service fee billed with each order:	PO Receipt cut off time:					
Drop Ship miscellaneous fees billed:	Days of week overnight is available: Monday					
Comments:	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, clinics and physician offices	Saturday Overnight receipt available:					
Restricted to retail pharmacy only:	PO Receipt Cut off time:					
Restricted to hospital, clinics, and physician offices only:	Output work and Phone: Phone #:					
Restricted from US territories? (explain in comments)	Order receipt method: Fax: Fax #:					
Comments:	EDI:					
	Overnight Fees apply:					
	Other fees apply:					
Other Data Information Required to Process PO:	Return Instructions					
Patient Procedure Date:	Contact # if product is received damaged:					
Physician Name:	Is product returnable for credit:					
Physician/Clinic Phone #	URL/Link to returns policy:					
Physician State License #	Special regulations or returns requirements for this product in certain states?					
Physician/Clinic DEA #:	If so, which states? Other requirements? Comments?					
Physician/Clinic Specialty:						
Miscellaneous Notes:						
	ADDITIONAL INFORMATION					
	Is product order for scheduled patient procedure?					
	Is product order for restocking purposes?					