



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

Version 2021		Introduction Type: Post Launch Change		x Final Version		Date: 7/12/2021																																																								
PRODUCT INFORMATION						SPECIAL HANDLING AND STORAGE REQUIREMENTS*																																																								
Company Name: Jubilant Cadista Pharmaceuticals Inc. Application: ANDA Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 201845 Medical Device Class, if applicable: DUNS: 022490515 Proprietary Name (If Applicable) and Established Name: Losartan - HCTZ Tablets Selling Unit NDC: 59746-338-90 Unit of Use NDC: UPC: 3-59746-338-90-9 UDI: CVX Code: MVX Code: Description: Losartan Potassium - Hydrochlorothiazide 100-12.5mg 90ct Tablet Active Ingredient(s): Losartan Potassium; Hydrochlorothiazide URL for Additional Product Information: www.cadista.com/products/full-product-list Address: 207 Kiley Drive City: Salisbury Key Contact: Jackie Emershaw Phone Number: (410) 912-3722 Product Therapeutic Classification: Antihypertensive State: MD Address 2: Zip: 21801 Email: Jackie.Emershaw@jubil.com Fax: (215) - 443 - 9646						a. Temperature – Indicate the USP temperature range for this product. Temperature Range: Controlled Room – between 20 and 25 C (68° – 77° F) Other Temperature Range Requirement (write in): Notes: Is this product to be shipped to customers on ice? No Is this product to be shipped to customers on dry ice? No b. Contact for temperature excursion questions: Name: Customer Service Number: (800) 313-4623 Group E-mail: customer.service@cadista.com c. Special regulations for product in any states? Special returns requirements for this product? No d. Store product (unit of sale) upright? Protect product (unit of sale) from light? No e. Shelf life: Initial shelf life at launch (if different): 24 Months																																																								
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION																																																										
The product is? No a legend device? No if yes, enter class # a product kit? No if yes, list NDCs of component parts reverse numbered? No co-licensed? No latex-free? Yes preservative-free? No correctional institution block? Yes opioid? No Cannabinoid? No If Unit Dose, is item bar coded to unit dose for hospital scanning? If Unit Dose, indicate NDC here:				Is the Product... Direct-Ship Only Is the Product... Neither Orphan Drug Status FDA Approval Status Allergens Present Country of Origin: US Is this product covered under the Trade Agreements Act (TAA)? Yes		Size: 90 count Strength: 100mg-12.5mg Dosage Form: TABLETS Product Shape: Oval Product Color: White Product Imprint: C / 338																																																								
FOR GENERIC DRUG PRODUCTS						ORDER INFORMATION																																																								
I. Orange Book Rating: AB II. Generic Equivalent to What Brand?: Hyzaar Authorized Generic: ☐ *If Authorized Generic, other section fields are not applicable						Unit of Sale <table><tr><td>☒</td><td>Bottle</td></tr><tr><td>☐</td><td>Box/Carton</td></tr><tr><td>☐</td><td>Ampule</td></tr><tr><td>☐</td><td>Glass</td></tr><tr><td>☐</td><td>Tube</td></tr><tr><td>☐</td><td>Vial Liquid Sgl</td></tr><tr><td>☐</td><td>Vial Liquid Multi</td></tr><tr><td>☐</td><td>Vial Powder Sgl</td></tr><tr><td>☐</td><td>Vial Power Multi</td></tr><tr><td>☐</td><td>Other: Write In</td></tr></table> What is the NDC selling unit? 1 bottle of 90 tablets (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity? Yes If Yes, how many of which package type? <table><tr><td>24</td><td>Each</td></tr><tr><td></td><td>Inner/Carton/Pack</td></tr><tr><td></td><td>Case</td></tr></table>		☒	Bottle	☐	Box/Carton	☐	Ampule	☐	Glass	☐	Tube	☐	Vial Liquid Sgl	☐	Vial Liquid Multi	☐	Vial Powder Sgl	☐	Vial Power Multi	☐	Other: Write In	24	Each		Inner/Carton/Pack		Case																													
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DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION						PHARMACY ORDER / BILL UNIT																																																								
Does supplier meet DSCSA definition of manufacturer? Yes Is product exempt from DSCSA? No If yes, select exemption: Other exemption - Write in: Is product repackaged? No Is product sold by manufacturer's exclusive distributor? No Has FDA granted waiver/exception/exemption for product? No If yes, attach documentation from FDA. GLN: 0359746000004 GCP: 0359746 If yes, was original product purchased direct from mfr? No Provide source manufacturer for repackaged product						Rec. sell unit to customer? 1 bottle of 90 tablets (Write-in, e.g. 1 Vial) Rx billing unit to pharmacy: <table><tr><td>☒</td><td>Each</td></tr><tr><td>☐</td><td>Gram</td></tr><tr><td>☐</td><td>Milliliter</td></tr></table>		☒	Each	☐	Gram	☐	Milliliter																																																	
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COST INFORMATION				WHOLESALE USE ONLY:																																																										
Regular Cost Invoice Cost (WAC) (\$) As of date:				Vendor #: Whsl. Code #: Fineline Code:																																																										

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING AND BARCODE.

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature:



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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		
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?			
Is the product a CA Prop 65 carcinogen?	☐ No		
Is the product a CA Prop 65 reproductive toxicant?	☐ No		
Does the product label bear a CA Prop 65 warning?	☐ No		
c. Contact Hazard?	☐ No		
d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)	☐ No		
e. Does the product contain DEHP?	☐ No		
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS)			
a. UN/Identification Number			
b. Proper Shipping Name			
c. DOT Hazard Class			
d. Packing Group			
e. Inhalation Hazard?	☐ No		
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)			
a. UN/Identification Number			
b. Proper Shipping Name			
c. DOT Hazard Class			
d. Packing Group			
e. Inhalation Hazard?	☐ No		
Is the product restricted for air shipment? If so, indicate restriction:		☐ No	
☐ Passenger			
☐ Cargo			
☐ Passenger & Cargo			
Is this a reportable quantity? ☐ No			
RQ Threshold:			
Is this a marine pollutant? ☐ No			
Is this product shipped utilizing an authorized DOT exception or Special Permit?			
☐ No	(if yes, identify method below)		
☐ Limited Quantity			
☐ Consumer Commodity, ORM-D			
☐ Small Quantity (49 CFR 173.4)			
☐ Special Permit, DOT-SP			
☐ Special Provision (listed in Column 7 of 49 CFR 172.101);			
SP#			
ADD'L STORAGE INFORMATION			
Is the Product...			
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:	
Schedule No.		Is it a scheduled listed chemical product?:	☐ No
CLASS OF TRADE RESTRICTION:			
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices		☐ Yes	
Restricted to retail pharmacy only:			
Restricted to hospital, clinics, and physician offices only:			
Restricted from US territories? (explain in comments)			
Comments:			
MISCELLANEOUS NOTES and/or Image of Product Barcode:			

SDS Hazard Classification	
☐ Organic	☐ Corrosive
☐ Inorganic	☐ Oxidizer
☐ Steroid/Androgen	☐ Contact Hazard
Does the product have an Aerosol class? If yes, identify No	
NFPA Storage Level:	
NFPA Storage Level:	
Is the product a NIOSH hazardous drug? ☐ No	
If yes, indicate which:	

Hazardous Waste Identification	
EPA Hazardous Waste Code:	Waste Characteristics

REMS or REGISTRY RESTRICTIONS	
Is there a REMS on this product? ☐ No	
If Yes, is it managed with a pharmacy registry?	
Website URL:	
Med Guide Required	☐ No
Limited Distribution Requirement	☐ No
Comments / Details: (For example, iPledge program?)	
REMS:	
REMS Program Manager Name:	
Supplier Manages REMS registry exclusively:	
Wholesale distributor support:	
Provider Name:	
Site Enrollment Number assigned by Supplier:	
DEA #:	
NCPDP#:	
NPI #:	
Comments	
Registry:	
Registry Program Contact Name:	
Phone:	
Comments	

RETURN INSTRUCTIONS	
Contact tel. # if product 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?	



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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: Fax Number: Fax Number: Phone No.: Site Address:	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 Priority Overnight receipt available: PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Order receipt method: Phone: Phone #: Fax: Fax #: EDI: Overnight Fees apply: Other fees apply:
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:	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?