



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

Version 2021 Introduction Type:  Post Launch Change  Final Version Date: 6/9/2023

## PRODUCT INFORMATION

**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:** 59746-339-10 **Unit of Use NDC:** **UPC:** 3-59746-339-10-4  
**UDI** **CVX Code:** **MXV Code:**  
**Description:** Losartan Potassium - Hydrochlorothiazide 100-25mg 1000ct Tablet  
**Active Ingredient(s):** Losartan Potassium; Hydrochlorothiazide  
**URL for Additional Product Information:** [www.cadista.com/products/full-product-list](http://www.cadista.com/products/full-product-list)  
**Address:** 207 Kiley Drive **Address 2:**  
**City:** Salisbury **State:** MD **Zip:** 21801  
**Key Contact:** Customer Service **Email:** [customer.service@cadista.com](mailto:customer.service@cadista.com)  
**Phone Number:** (800) 313-4623 **Fax:** N/A  
**Product Therapeutic Classification:** Antihypertensive

## SPECIAL HANDLING AND STORAGE REQUIREMENTS\*

**a. Temperature – Indicate the USP temperature range for this product.**  
**Temperature Range**   
**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](mailto:customer.service@cadista.com)  
**c. Special regulations for product in any states?**  No  
 Special returns requirements for this product?  No  
**d. Store product (unit of sale) upright?**  No  
 Protect product (unit of sale) from light?  No  
**e. Shelf life:**  24 Months  
 Initial shelf life at launch (if different):

## ADDITIONAL PRODUCT INFORMATION

**The product is?**  
 a legend device?  No  
 if yes, enter class #  
 a product kit?  No  
 if yes, list NDCs of component parts reverse numbered?  
 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**  Neither   
**Is the Product... Orphan Drug Status**  
**FDA Approval Status**  
**Allergens Present**  
**Country of Origin**   
 Is this product covered under the Trade Agreements Act (TAA)?  Yes

## PRODUCT DESCRIPTION INFORMATION

**Size:** 1000 count  
**Strength:** 100mg-25mg  
**Dosage Form:** TABLETS  
**Product Shape:** Oval  
**Product Color:** Yellow  
**Product Imprint:** C / 339

## ORDER INFORMATION

**Unit of Sale**  
 Bottle  
 Box/Carton  
 Ampule  
 Glass  
 Tube  
 Vial Liquid Sgl  
 Vial Liquid Multi  
 Vial Powder Sgl  
 Vial Power Multi  
 Other: Write In  
**What is the NDC selling unit?** 1 bottle of 1000 tablets  
 (Write-in, e.g. 1 Box of 10 Vials)  
**Minimum order quantity?**  Yes  
**If Yes, how many of which package type?**  
 Each  
 Inner/Carton/Pack  
 Case

## FOR GENERIC DRUG PRODUCTS

Authorized Generic \*If Authorized Generic, other section fields are not applicable  
**I. Orange Book Rating:**   
**II. Generic Equivalent to What Brand?:**

## PHARMACY ORDER / BILL UNIT

**Rec. sell unit to customer?** 1 bottle of 1000 tablets  
 (Write-in, e.g. 1 Vial)  
**Rx billing unit to pharmacy:**  
 Each  
 Gram  
 Milliliter

## DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

**Does supplier meet DSCSA definition of manufacturer?**  Yes  
**Is product exempt from DSCSA?**  No  
**GLN:** 0359746000004  
**GCP:** 0359746  
**If yes, was original product purchased direct from mfr?**   
**Provide source manufacturer for repackaged product**

**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.

## ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	1.27	3.5	3.5	6.4	78.40	1
Box/Carton/Bundle/Inner Pack:					0.00	
Case:	18.22	14.25	10.75	8	1225.50	12
Pallet:					0.00	

## GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00359746339104	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	12		40359746339102	
<input type="checkbox"/> Pallet				

## COST INFORMATION

**Regular Cost**  
**Invoice Cost (WAC) (\$)** \$290.00  
 As of date:  
**Vendor #:**  
**Whsl. Code #:**  
**Fineline Code:**



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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)  No

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)  No

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#

### SDS Hazard Classification

Organic  Corrosive  
 Inorganic  Oxidizer  
 Steroid/Androgen  Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:  No  
 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:  Phone:   
 Supplier Manages REMS registry exclusively:   
 Wholesale distributor support:   
 Provider Name:  DEA #:   
 Site Enrollment Number assigned by Supplier:  NCPDP#:   
 NPI #:

Comments

**Registry:**

Registry Program Contact Name:  Phone:   
 Comments

### 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:

### 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?

### MISCELLANEOUS NOTES and/or Image of Product Barcode:

