



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

Version 2021

Introduction Type:  Post Launch Change

Final Version

Date: 6/17/2024

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
<b>Company Name:</b> Jubilant Cadista Pharmaceuticals Inc. <b>Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):</b> 201845 <b>Medical Device Class, if applicable:</b> <b>DUNS:</b> 022490515 <b>Proprietary Name (If Applicable) and Established Name:</b> Losartan - HCTZ Tablets <b>Selling Unit NDC:</b> 59746-338-10 <b>Unit of Use NDC:</b> <b>UPC:</b> 3-59746-338-10-7 <b>UDI</b> <b>CVX Code:</b> <b>MXV Code:</b>		<b>Application:</b> ANDA <b>Description:</b> Losartan Potassium - Hydrochlorothiazide 100-12.5mg 1000ct Tablet <b>Active Ingredient(s):</b> Losartan Potassium; Hydrochlorothiazide <b>URL for Additional Product Information:</b> <a href="http://www.cadista.com/products/full-product-list">www.cadista.com/products/full-product-list</a> <b>Address:</b> 790 Township Line Road <b>City:</b> Yardley <b>Key Contact:</b> Customer Service <b>Phone Number:</b> (800) 313-4623 <b>Product Therapeutic Classification:</b> Antihypertensive		<b>a. Temperature – Indicate the USP temperature range for this product.</b> <b>Temperature Range</b> <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>  <b>Other Temperature Range Requirement (write in)</b> <b>Notes</b>  Is this product to be shipped to customers on ice? <input type="checkbox"/> No Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No		<b>b. Contact for temperature excursion questions:</b> <b>Name:</b> Customer Service <b>Number:</b> (800) 313-4623 <b>Group E-mail:</b> <a href="mailto:customer.service@cadista.com">customer.service@cadista.com</a>	
<b>Address 2:</b> Suite 325 <b>State:</b> PA <b>Zip:</b> 19067 <b>Email:</b> <a href="mailto:customer.service@cadista.com">customer.service@cadista.com</a> <b>Fax:</b> N/A		<b>c. Special regulations for product in any states?</b> <input type="checkbox"/> No Special returns requirements for this product? <input type="checkbox"/> No		<b>d. Store product (unit of sale) upright?</b> <input type="checkbox"/> No <b>Protect product (unit of sale) from light?</b> <input type="checkbox"/> No			
<b>e. Shelf life:</b> <input type="checkbox"/> 24 Months <b>Initial shelf life at launch (if different):</b> <input type="checkbox"/> Months		<b>ORDER INFORMATION</b>					
<b>Unit of Sale</b> <input checked="" type="checkbox"/> Bottle <input type="checkbox"/> Box/Carton <input type="checkbox"/> Ampule <input type="checkbox"/> Glass <input type="checkbox"/> Tube <input type="checkbox"/> Vial Liquid Sgl <input type="checkbox"/> Vial Liquid Multi <input type="checkbox"/> Vial Powder Sgl <input type="checkbox"/> Vial Power Multi <input type="checkbox"/> Other: Write In		<b>What is the NDC selling unit?</b> <input type="text" value="1 bottle of 1000 tablets"/> (Write-in, e.g. 1 Box of 10 Vials)		<b>Minimum order quantity?</b> <input type="checkbox"/> Yes			
<b>If Yes, how many of which package type?</b> <input type="text" value="12"/> Each <input type="text"/> Inner/Carton/Pack <input type="text"/> Case		<b>PHARMACY ORDER / BILL UNIT</b>					
<b>Rec. sell unit to customer?</b> <input type="text" value="1 bottle of 1000 tablets"/> (Write-in, e.g. 1 Vial)		<b>Rx billing unit to pharmacy:</b> <input checked="" type="checkbox"/> Each <input type="checkbox"/> Gram <input type="checkbox"/> Milliliter					
<b>FOR GENERIC DRUG PRODUCTS</b>							
<b>I. Orange Book Rating:</b> <input type="text" value="AB"/>		<input type="checkbox"/> Authorized Generic      *If Authorized Generic, other section fields are not applicable					
<b>II. Generic Equivalent to What Brand?:</b> <input type="text" value="Hyzaan@"/>							
<b>DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION</b>							
<b>Does supplier meet DSCSA definition of manufacturer?</b> <input type="checkbox"/> Yes <b>Is product exempt from DSCSA?</b> <input type="checkbox"/> No		<b>GLN:</b> <input type="text" value="0359746000004"/>					
<b>If yes, select exemption:</b> <b>Other exemption - Write in:</b>		<b>GCP:</b> <input type="text" value="0359746"/>					
<b>Is product repackaged?</b> <input type="checkbox"/> No <b>Is product sold by manufacturer's exclusive distributor?</b> <input type="checkbox"/> No <b>Has FDA granted waiver/exception/exemption for product?</b> <input type="checkbox"/> No <b>If yes, attach documentation from FDA.</b>		<b>If yes, was original product purchased direct from mfr?</b> <input type="checkbox"/> Yes <b>Provide source manufacturer for repackaged product</b>					
<b>GTIN AND HIBCC PRODUCT INFORMATION</b>							
<b>Saleable Unit of Measure</b> <input checked="" type="checkbox"/> Item/Each <input type="checkbox"/> Box/Carton/Bundle/Inner Pack <input checked="" type="checkbox"/> Case <input type="checkbox"/> Pallet		<b>Saleable Quantity</b> <input type="text" value="1"/> <input type="text" value="12"/>		<b>HIBCC</b> <input type="text"/> <input type="text"/>			
		<b>GTIN-14</b> <input type="text" value="00359746338107"/> <input type="text" value="40359746338105"/>		<b>Unit of Use GTIN-14</b> <input type="text"/>			
<b>ITEM AND PACKING INFORMATION</b>							
	<b>Weight Lbs.</b>	<b>Dimensions (US msmts.)</b>			<b>Volume (Cube)</b>	<b>Saleable # Pieces</b>	
	<b>Depth</b>	<b>Width</b>	<b>Height</b>				
<b>Item/Each:</b>	1.27	1.9	1.9	4	14.44	1	
<b>Box/Carton/Bundle/Inner Pack:</b>					0.00		
<b>Case:</b>	18.27	14.25	10.75	8	1225.50	12	
<b>Pallet:</b>					0.00		
<b>COST INFORMATION</b>							
<b>Regular Cost</b> <b>Invoice Cost (WAC) (\$)</b>		<input type="text" value="\$290.00"/>		<b>Vendor #:</b> <b>Whsl. Code #:</b> <b>Fineline Code:</b>			
<b>As of date:</b>		<input type="text"/>		<input type="text"/>			
<b>WHOLESALE USE ONLY:</b>							
<b>Signature:</b> <input type="text"/>							

\*Please provide any additional information on page 2.

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

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:

- Passenger  No
- Cargo  No
- Passenger & Cargo  No

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  Yes      Controlled Substance Code
- Controlled by State(s)?  No  Yes      Listed Chemical (List I or II)  No  Yes
- ARCOS Reportable?  No  Yes      If yes, indicate which:
- Schedule No.       Is it a scheduled listed chemical product?:  No  Yes

### CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes  No
- Restricted to retail pharmacy only:
- Restricted to hospital, clinics, and physician offices only:
- Restricted from US territories? (explain in comments)
- Comments:

### 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

Is the product a NIOSH hazardous drug? If yes, indicate which:  No

### Hazardous Waste Identification

EPA Hazardous Waste Code:  Waste Characteristics:

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?  No  Yes  
If Yes, is it managed with a pharmacy registry?  No  Yes  
Website URL:

Med Guide Required  No  Yes  
Limited Distribution Requirement  No  Yes  
Comments / Details: (For example, iPledge program?)

**REMS:**  
REMS Program Manager Name:  Phone:   
Supplier Manages REMS registry exclusively:  No  Yes  
Wholesale distributor support:  No  Yes  
Provider Name:  DEA #:   
Site Enrollment Number assigned by Supplier:  NCPDP#:   
NPI #:

Comments

**Registry:**  
Registry Program Contact Name:  Phone:   
Comments

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:   
Is product returnable for credit:  No  Yes  
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:

