



# 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** **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):** 201170  
**Medical Device Class, if applicable:** \_\_\_\_\_  
**DUNS:** 022490515  
**Proprietary Name (If Applicable) and Established Name:** Losartan Potassium Tablets  
**Selling Unit NDC:** 59746-335-90 **Unit of Use NDC:** \_\_\_\_\_ **UPC:** 3-59746-335-90-8  
**UDI** \_\_\_\_\_ **CVX Code:** \_\_\_\_\_ **MXV Code:** \_\_\_\_\_  
**Description:** Losartan Potassium 100mg 90ct Tablet  
**Active Ingredient(s):** Losartan Potassium  
**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

**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:**  Months  
 Initial shelf life at launch (if different):  Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? if yes, enter class # a product kit?	<input type="checkbox"/> No	Is the Product... Direct-Ship Only	<input type="checkbox"/>
if yes, list NDCs of component parts reverse numbered?	<input type="checkbox"/> No	Is the Product... Orphan Drug Status	<input type="checkbox"/> Neither
co-licensed?	<input type="checkbox"/> No	FDA Approval Status	<input type="text" value=""/>
latex-free?	<input type="checkbox"/> No	Allergens Present	<input type="text" value=""/>
preservative-free?	<input type="checkbox"/> Yes	Country of Origin	<input type="text" value="US"/>
correctional institution block? opioid?	<input type="checkbox"/> No	Is this product covered under the Trade Agreements Act (TAA)?	<input type="checkbox"/> Yes
Cannabinoid?	<input type="checkbox"/> No		
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>		
If Unit Dose, indicate NDC here:	<input type="text" value=""/>		
		Size:	<input type="text" value="90 count"/>
		Strength:	<input type="text" value="100mg"/>
		Dosage Form:	<input type="text" value="TABLETS"/>
		Product Shape:	<input type="text" value="Oval, Scored"/>
		Product Color:	<input type="text" value="Green"/>
		Product Imprint:	<input type="text" value="C / 335"/>

**ORDER INFORMATION**

Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	<input type="text" value="1 bottle of 90 tablets"/>
<input type="checkbox"/> Box/Carton	<input type="text" value="(Write-in, e.g. 1 Box of 10 Vials)"/>
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity? <input type="checkbox"/> Yes
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	
<input type="checkbox"/> Vial Powder Sgl	If Yes, how many of which package type?
<input type="checkbox"/> Vial Power Multi	<input type="text" value="48"/> Each
<input type="checkbox"/> Other: Write In	<input type="text" value=""/> Inner/ Carton/ Pack
	<input type="text" value=""/> 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?**   
 (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  No  
 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?   
 Provide source manufacturer for repackaged product: \_\_\_\_\_

**ITEM AND PACKING INFORMATION**

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.13	1.9	1.9	4	14.44	1
Box/ Carton/ Bundle/ Inner Pack:					0.00	
Case:	7.95	15.5	11.75	5.25	956.16	48
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		00359746335908	
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack				
<input checked="" type="checkbox"/> Case	48		40359746335906	
<input type="checkbox"/> Pallet				

**COST INFORMATION** **WHOLESALE USE ONLY:**

**Regular Cost** \_\_\_\_\_  
**Invoice Cost (WAC) (\$)**   
 As of date: \_\_\_\_\_

**Vendor #:** \_\_\_\_\_  
**Whsl. Code #:** \_\_\_\_\_  
**Fineline Code:** \_\_\_\_\_



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Version 2021

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

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
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- 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

### 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:

