



# Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type:  Pre-Launch Change  Post Launch Change Final Version

Date: 10/29/2020

**PRODUCT INFORMATION**

Company Name: Jubilat Cadista Pharmaceuticals Inc. Application: ANDA  
 Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): A201845  
 DUNS: 022490515  
 Proprietary Name (If Applicable) and Established Name: Losartan Potassium  
 Selling Unit NDC: 59746-0339-90 Individual Unit NDC: CVX Code: MVX Code: 3-59746-339-90-6  
 Description: Losartan HCTZ 100-25mg Tablets 90ct.  
 Active Ingredient(s): Losartan Hydrochlorothiazide  
 URL for Additional Product Information: www.cadista.com  
 Address: 207 Kiley Drive City: Salisbury State: MD Zip: 21801  
 Key Contact: Jackie Emershaw Email: Jackie.Emershaw@cadista.com  
 Phone Number: (410) 912-3722 Fax: (215) 443-9646  
 Product Therapeutic Classification:

**ADDITIONAL PRODUCT INFORMATION**

Is the Product...  
 a legend device?  Yes  
 reverse numbered?  No  
 co-licensed?  No  
 Is the Product...  Direct-Ship Only  
 Is the Product...  
 If Unit Dose, is item bar coded to unit dose for hospital scanning?   
 If Unit Dose NDC, indicate NDC here:  
 Country of Origin:  
 Is this product covered under the Trade Agreements Act (TAA)?  Yes

**PRODUCT DESCRIPTION INFORMATION**

Size: 90ct  
 Strength: 100-25mg  
 Dosage Form: TAB  
 Product Shape: Oval  
 Product Color: Yellow  
 Product Imprint: Debossed C | 339

**FOR GENERIC DRUG PRODUCTS**

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

**DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION**

Does supplier meet DSCSA definition of manufacturer?  Yes  No  
 Is product exempt from DSCSA?  Yes  No  
 If yes, select exemption:  
 Other exemption - Write in:  
 Is product repackaged?  Yes  No  
 Is product sold by manufacturer's exclusive distributor?  Yes  No  
 Has FDA granted waiver/exception/exemption for product?  Yes  No  
 GLN: 0359746000004  
 If Yes, was original product purchased direct from mfr?  
 If yes, attach documentation from FDA.

**GTIN PRODUCT INFORMATION**

	Serialized?	If not, when?	Items aggregated?	Level		Saleable Unit		Quantity	GTIN-14
				Item	Box/Case/Pallet	Unit	Unit		
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1	00359746339906
<input checked="" type="checkbox"/>	<input type="checkbox"/>			<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	24	40359746339904
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<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

**SPECIAL HANDLING AND STORAGE REQUIREMENTS\***

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):  
 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 Support  
 Number: (800) 313-4623  
 Group E-mail:  
 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  24 Months

**ORDER INFORMATION**

Unit of Sale:  Bottle  Box/Case  Ampule  Glass  Tube  Vial Liquid Sgl  Vial Liquid Multi  Vial Powder Sgl  Vial Powder Multi  Other: Write In  
 What is the NDC selling unit?  
 1 Case of 24 Bottles  
 (Write-in, e.g. 1 Box of 10 Vials)  
 Minimum order quantity?  Yes  
 If Yes, how many of which package type?  
 24 Each  Inner/Case/Pack  Case

**PHARMACY ORDER / BILL UNIT**

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

**ITEM AND PACKING INFORMATION**

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Box/Case/Bundle/Inner Pack:	0.18	2	4	2	16	1
Case:	5.21	11.5	5	7.75	445.63	24
Pallet:					0	
UPC:	Case:					
	Carton:					

**COST INFORMATION**

Regular Cost  
 Invoice Cost (WAC) (\$): \$26.10  
 Federal Excise Tax Per Unit of Sale  
 As of date:  
 Vendor #:  
 Whsl. Code #:  
 FineLine Code:

**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 or 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?

Is the product restricted for air shipment? If so, indicate restriction:

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 by State(s)? No

ARCOS Reportable? No

Schedule No. (inc. N for non-narcotic)

Controlled Substance Code

Listed Chemical (List I or II)

If yes, indicate which:

Is it a scheduled listed chemical product?:

**CLASS OF TRADE RESTRICTION:**

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes

Restricted to retail pharmacy only: No

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments:

**SDS Hazard Classification**

Organic  Corrosive  
 Inorganic  Oxidizer  
 Steroid/Androgen  Contact Hazard

Aerosol Class; Identify NFPA Storage Level:

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

**Hazardous Waste Identification**

EPA Hazardous Waste Code:

**REMS or REGISTRY RESTRICTIONS**

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

Comments / Details: (For example, iPledge program?)

**REMS:** No

REMS Program Manager Name:  Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:  
 Provider Name:   
 Site Enrollment Number assigned by Supplier:

DEA #:   
 PCPDP #:   
 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:**

**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																													
<p>Purchase orders may be accepted by:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">a. EDI</td> <td style="width: 10%; text-align: center;"><input type="checkbox"/></td> <td style="width: 10%; text-align: center;">Yes</td> <td style="width: 20%;"></td> <td style="width: 15%;"></td> </tr> <tr> <td>b. Autofax</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;">Yes</td> <td>Fax Number:</td> <td><input style="width: 100%;" type="text"/></td> </tr> <tr> <td>c. Fax</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;">Yes</td> <td>Fax Number:</td> <td><input style="width: 100%;" type="text"/></td> </tr> <tr> <td>d. Phone only</td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> <td>Phone No.:</td> <td><input style="width: 100%;" type="text"/></td> </tr> <tr> <td>e. Supplier Web Site only</td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> <td>Site Address:</td> <td><input style="width: 100%;" type="text"/></td> </tr> </table> <p>Minimum Order Quantity: <input style="width: 50px;" type="text" value="24"/></p> <p>Supplier's Customer Service Number: <input style="width: 100%;" type="text" value="(410) 912-3722"/></p> <p>Contracted 3PL company / contact #:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Name:</td> <td><input style="width: 80%;" type="text"/></td> </tr> <tr> <td>Phone:</td> <td><input style="width: 80%;" type="text"/></td> </tr> </table>	a. EDI	<input type="checkbox"/>	Yes			b. Autofax	<input type="checkbox"/>	Yes	Fax Number:	<input style="width: 100%;" type="text"/>	c. Fax	<input type="checkbox"/>	Yes	Fax Number:	<input style="width: 100%;" type="text"/>	d. Phone only	<input type="checkbox"/>		Phone No.:	<input style="width: 100%;" type="text"/>	e. Supplier Web Site only	<input type="checkbox"/>		Site Address:	<input style="width: 100%;" type="text"/>	Name:	<input style="width: 80%;" type="text"/>	Phone:	<input style="width: 80%;" type="text"/>	<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input style="width: 150px;" type="text"/></p> <p>Shipping lead time of PO: <input style="width: 50px;" type="text"/> Hours <input style="width: 50px;" type="text"/> Days</p> <p>Ships same day for next day receipt: <input style="width: 50px;" type="text"/></p> <p>Ships for second day receipt: <input style="width: 50px;" type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input style="width: 50px;" type="text"/></p>
a. EDI	<input type="checkbox"/>	Yes																												
b. Autofax	<input type="checkbox"/>	Yes	Fax Number:	<input style="width: 100%;" type="text"/>																										
c. Fax	<input type="checkbox"/>	Yes	Fax Number:	<input style="width: 100%;" type="text"/>																										
d. Phone only	<input type="checkbox"/>		Phone No.:	<input style="width: 100%;" type="text"/>																										
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Name:	<input style="width: 80%;" type="text"/>																													
Phone:	<input style="width: 80%;" type="text"/>																													
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing																													
<p>Expedited freight fees billed with each order: <input style="width: 50px;" type="text"/></p> <p>Drop Ship service fee billed with each order: <input style="width: 50px;" type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input style="width: 50px;" type="text"/></p> <p>Comments: <input style="width: 100%; height: 50px;" type="text"/></p>	<p><b>Overnight receipt available:</b> <input style="width: 50px;" type="text"/></p> <p>PO Receipt cut off time: <input style="width: 150px;" type="text"/></p> <p>Days of week overnight is available:</p> <table style="width: 100%; border-collapse: collapse;"> <tr><td><input type="checkbox"/></td><td>Monday</td></tr> <tr><td><input type="checkbox"/></td><td>Tuesday</td></tr> <tr><td><input type="checkbox"/></td><td>Wednesday</td></tr> <tr><td><input type="checkbox"/></td><td>Thursday</td></tr> <tr><td><input type="checkbox"/></td><td>Friday</td></tr> </table> <p><b>Priority Overnight receipt available:</b> <input style="width: 50px;" type="text"/></p> <p>PO Receipt Cut off time: <input style="width: 150px;" type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input style="width: 50px;" type="text"/></p> <p>PO Receipt Cut off time: <input style="width: 150px;" type="text"/></p> <p>Order receipt method:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Phone:</td> <td style="width: 30%;"><input style="width: 100%;" type="text"/></td> <td style="width: 10%;">Phone #:</td> <td style="width: 40%;"><input style="width: 100%;" type="text"/></td> </tr> <tr> <td>Fax:</td> <td><input style="width: 100%;" type="text"/></td> <td>Fax #:</td> <td><input style="width: 100%;" type="text"/></td> </tr> <tr> <td>EDI:</td> <td><input style="width: 100%;" type="text"/></td> <td></td> <td></td> </tr> </table> <p>Overnight Fees apply: <input style="width: 50px;" type="text"/></p> <p>Other fees apply: <input style="width: 50px;" type="text"/></p>	<input type="checkbox"/>	Monday	<input type="checkbox"/>	Tuesday	<input type="checkbox"/>	Wednesday	<input type="checkbox"/>	Thursday	<input type="checkbox"/>	Friday	Phone:	<input style="width: 100%;" type="text"/>	Phone #:	<input style="width: 100%;" type="text"/>	Fax:	<input style="width: 100%;" type="text"/>	Fax #:	<input style="width: 100%;" type="text"/>	EDI:	<input style="width: 100%;" type="text"/>									
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Fax:	<input style="width: 100%;" type="text"/>	Fax #:	<input style="width: 100%;" type="text"/>																											
EDI:	<input style="width: 100%;" type="text"/>																													
Class of Trade Restriction:	Return Instructions																													
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input style="width: 50px;" type="text"/></p> <p>Restricted to retail pharmacy only: <input style="width: 50px;" type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input style="width: 50px;" type="text"/></p> <p>Restricted from US territories? (explain in comments) <input style="width: 50px;" type="text"/></p> <p>Comments: <input style="width: 100%; height: 50px;" type="text"/></p>	<p>Contact # if product is received damaged: <input style="width: 100%;" type="text"/></p> <p>Is product returnable for credit: <input style="width: 50px;" type="text"/></p> <p>URL/Link to returns policy: <input style="width: 100%;" type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input style="width: 50px;" type="text"/></p> <p>If so, which states? Other requirements? Comments?  <input style="width: 100%; height: 40px;" type="text"/></p>																													
Other Data Information Required to Process PO:	ADDITIONAL INFORMATION																													
<p>Patient Procedure Date: <input style="width: 100%;" type="text"/></p> <p>Physician Name: <input style="width: 100%;" type="text"/></p> <p>Physician/Clinic Phone #: <input style="width: 100%;" type="text"/></p> <p>Physician State License #: <input style="width: 100%;" type="text"/></p> <p>Physician/Clinic DEA #: <input style="width: 100%;" type="text"/></p> <p>Physician/Clinic Specialty: <input style="width: 100%;" type="text"/></p>	<p>Is product order for scheduled patient procedure? <input style="width: 50px;" type="text"/></p> <p>Is product order for restocking purposes? <input style="width: 50px;" type="text"/></p>																													
Miscellaneous Notes:																														
<input style="width: 100%; height: 80px;" type="text"/>																														