



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: New Drug Post Launch Change

Final Version

Date: 2/12/2021

PRODUCT INFORMATION

Company Name: Jubilent 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: 59746-0338-90 Individual Unit NDC: CVX Code: MVX Code: 3-59746-338-90-9
 Description: Losartan HCTZ 100-12.5mg 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: Antihypertensive

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: 100-12.5mg
 Dosage Form: TAB
 Product Shape: Oval
 Product Color: White
 Product Imprint: Debossed C | 338

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

GTIN PRODUCT INFORMATION

	Serialized? If not, when? Items aggregated?	Level	Saleable Unit		Quantity	GTIN-14
			Item	Unit		
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Box/ Carton/ Bundle/ Inner Pack	<input checked="" type="checkbox"/>	2D	1	00359746338909
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Case	<input checked="" type="checkbox"/>	2D	24	40359746338907
		Pallet		2D		
				2D		
				2D		
				2D		
				2D		
				2D		

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/ Carton
 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/ Carton/ 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/ Carton/ Bundle/ Inner Pack:	0.12	1.9	4	1.9	14.44	1
Case:	3.7	11.75	5.25	8	493.5	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 #:
 Finline 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: (410) 912-3722

Is product returnable for credit:

URL/Link to returns policy: www.cadista.com

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: 30%;"></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: <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: <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.: <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: <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: 30%;">Name:</td> <td><input style="width: 100%;" type="text"/></td> </tr> <tr> <td>Phone:</td> <td><input style="width: 100%;" 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: 100%;" type="text"/>	Phone:	<input style="width: 100%;" type="text"/>	<p>Purchase order daily receipt cut off time by supplier</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>
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Phone:	<input style="width: 100%;" 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>Overnight receipt available: <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>Priority Overnight receipt available: <input style="width: 50px;" type="text"/></p> <p>PO Receipt Cut off time: <input style="width: 150px;" type="text"/></p> <p>Saturday Overnight receipt available: <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: 30%;">Phone:</td> <td style="width: 20%;"><input style="width: 100%;" type="text"/></td> <td style="width: 20%;">Phone #:</td> <td style="width: 30%;"><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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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"/>																									