



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

Version 2021

Introduction Type: Post Launch Change

Final Version

Date: 7/12/2021

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): 201845 Medical Device Class, if applicable: DUNS: 022490515 Proprietary Name (If Applicable) and Established Name: Losartan - HCTZ Tablets Selling Unit NDC: 59746-339-30 Unit of Use NDC: UPC: 3-59746-339-30-2 UDI CVX Code: MVX Code: Description: Losartan Potassium - Hydrochlorothiazide 100-25mg 30ct Tablet Active Ingredient(s): Losartan Potassium; Hydrochlorothiazide URL for Additional Product Information: www.cadista.com/products/full-product-list Address: 207 Kiley Drive Address 2: City: Salisbury State: MD Zip: 21801 Key Contact: Jackie Emershaw Email: Jackie.Emershaw@jubl.com Phone Number: (410) 912-3722 Fax: (215) - 443 - 9646 Product Therapeutic Classification: Antihypertensive		a. Temperature – Indicate the USP temperature range for this product. Temperature Range: <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/> Other Temperature Range Requirement (write in): Notes: 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. Contact for temperature excursion questions: Name: Customer Service Number: (800) 313-4623 Group E-mail: customer.service@cadista.com c. Special regulations for product in any states? Special returns requirements for this product? <input type="checkbox"/> No d. Store product (unit of sale) upright? <input type="checkbox"/> No e. Shelf life: Protect product (unit of sale) from light? <input type="checkbox"/> No Initial shelf life at launch (if different): <input type="text" value="24"/> Months																																											
ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION																																											
The product is? <input type="checkbox"/> No a legend device? if yes, enter class # a product kit? <input type="checkbox"/> No if yes, list NDCs of component parts reverse numbered? <input type="checkbox"/> No co-licensed? <input type="checkbox"/> No latex-free? <input checked="" type="checkbox"/> Yes preservative-free? <input type="checkbox"/> No correctional institution block? <input checked="" type="checkbox"/> Yes opioid? <input type="checkbox"/> No Cannabinoid? <input type="checkbox"/> No If Unit Dose, is item bar coded to unit dose for hospital scanning? If Unit Dose, indicate NDC here:		Is the Product... <input type="checkbox"/> Direct-Ship Only Is the Product... <input type="checkbox"/> Neither Orphan Drug Status FDA Approval Status Allergens Present Country of Origin <input type="text" value="US"/> Is this product covered under the Trade Agreements Act (TAA)? <input checked="" type="checkbox"/> Yes																																											
		Size: 30 count Strength: 100mg-25mg Dosage Form: TABLETS Product Shape: Oval Product Color: Yellow Product Imprint: C / 339																																											
FOR GENERIC DRUG PRODUCTS																																													
I. Orange Book Rating: <input type="text" value="AB"/> II. Generic Equivalent to What Brand?: <input type="text" value="Hyzaar"/>		<input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable																																											
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION																																													
Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes Is product exempt from DSCSA? <input type="checkbox"/> No If yes, select exemption: Other exemption - Write in: Is product repackaged? <input type="checkbox"/> No Is product sold by manufacturer's exclusive distributor? <input type="checkbox"/> No Has FDA granted waiver/exception/exemption for product? <input type="checkbox"/> No If yes, attach documentation from FDA.		GLN: 0359746000004 GCP: 0359746 If yes, was original product purchased direct from mfr? <input type="checkbox"/> Provide source manufacturer for repackaged product																																											
GTIN AND HIBCC PRODUCT INFORMATION																																													
Saleable Unit of Measure <input checked="" type="checkbox"/> Item/Each <input type="checkbox"/> Box/Carton/Bundle/Inner Pack <input checked="" type="checkbox"/> Case <input type="checkbox"/> Pallet		Saleable Quantity <input type="text" value="1"/> HIBCC GTIN-14 00359746339302 Unit of Use GTIN-14 40359746339300																																											
COST INFORMATION		WHOLESALE USE ONLY:																																											
Regular Cost Invoice Cost (WAC) (\$) \$8.54 As of date:		Vendor #: Whsl. Code #: Fineline Code:																																											
ORDER INFORMATION																																													
Unit of Sale <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		What is the NDC selling unit? <input type="text" value="1 bottle of 30 tablets"/> (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity? <input type="checkbox"/> Yes If Yes, how many of which package type? <input type="text" value="48"/> Each <input type="text"/> Inner/Carton/Pack <input type="text"/> Case																																											
PHARMACY ORDER / BILL UNIT																																													
Rec. sell unit to customer? <input type="text" value="1 bottle of 30 tablets"/> (Write-in, e.g. 1 Vial)		Rx billing unit to pharmacy: <input checked="" type="checkbox"/> Each <input type="checkbox"/> Gram <input type="checkbox"/> Milliliter																																											
ITEM AND PACKING INFORMATION																																													
		<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th>Weight Lbs.</th> <th colspan="3">Dimensions (US msmts.)</th> <th>Volume (Cube)</th> <th>Saleable # Pieces</th> </tr> <tr> <th></th> <th></th> <th>Depth</th> <th>Width</th> <th>Height</th> <th></th> <th></th> </tr> </thead> <tbody> <tr> <td>Item/Each:</td> <td>0.11</td> <td>1.9</td> <td>1.9</td> <td>4</td> <td>14.44</td> <td>1</td> </tr> <tr> <td>Box/Carton/Bundle/Inner Pack:</td> <td></td> <td></td> <td></td> <td></td> <td>0.00</td> <td></td> </tr> <tr> <td>Case:</td> <td>6.07</td> <td>15.25</td> <td>11.5</td> <td>5</td> <td>876.88</td> <td>48</td> </tr> <tr> <td>Pallet:</td> <td></td> <td></td> <td></td> <td></td> <td>0.00</td> <td></td> </tr> </tbody> </table>			Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces			Depth	Width	Height			Item/Each:	0.11	1.9	1.9	4	14.44	1	Box/Carton/Bundle/Inner Pack:					0.00		Case:	6.07	15.25	11.5	5	876.88	48	Pallet:					0.00	
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Case:	6.07	15.25	11.5	5	876.88	48																																							
Pallet:					0.00																																								
ATTACHMENTS AND SIGNATURE																																													
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE. *Please provide any additional information on page 2. 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 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:

MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE

SDS Hazard Classification

- Organic Corrosive
- Inorganic Oxidizer
- Steroid/Androgen Contact Hazard

Does the product have an Aerosol class? If yes, identify No

NFPA Storage Level:

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?



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