



# Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type:  Final VersionDate: 

| PRODUCT INFORMATION   |                                       |
|---|---------------------------------------|
| Company Name:   | Jubilant 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:   | 59746-0337-30                         |
| Individual Unit NDC:  |                                       |
| UPC:  | 3-59746-337-30-8                      |
| UDI   |                                       |
| CVX Code:   |                                       |
| MVX Code:   |                                       |
| Description:  | Losartan HCTZ 50-12.5mg Tablets 30ct. |
| Active Ingredient(s):   | Losartan Hydrochlorothiazide          |
| URL for Additional Product Information:                             | www.cadista.com                       |
| Address:  | 207 Kiley Drive                       |
| City:   | Salisbury                             |
| Key Contact:  | Jackie Emershaw                       |
| Phone Number:   | (410) 912-3722                        |
| Product Therapeutic Classification:                                 | Antihypertensive                      |

| 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?                     | 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:  |   |
| Initial shelf life at launch (if different):                          | <input type="text" value="24"/> Months              |

| 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... Direct-Ship Only?                                 |     |
| 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:                           | 30ct             |
| Strength:                       | 50-12.5mg        |
| Dosage Form:                    | TAB              |
| Product Shape:                  | Oval             |
| Product Color:                  | Yellow           |
| Product Imprint:                | Debossed C   337 |

| ORDER INFORMATION                          |   |
|--|---|
| Unit of Sale                               | What is the NDC selling unit?                       |
| <input checked="" type="checkbox"/> Bottle | 1 Case of 24 Bottles                                |
| <input type="checkbox"/> Box/ Carton       | (Write-in, e.g. 1 Box of 10 Vials)                  |
| <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 Powder Multi |   |
| <input type="checkbox"/> Other: Write In   |   |
|  | Minimum order quantity? Yes                         |
|  | If Yes, how many of which package type?             |
|  | <input type="text" value="24"/> Each                |
|  | <input type="text" value="24"/> Inner/ Carton/ Pack |
|  | <input type="text" value="24"/> Case                |

| FOR GENERIC DRUG PRODUCTS              |   |
|--|---|
| I. Orange Book Rating:                 | AB  |
| II. Generic Equivalent to What Brand?: | Hyzaar®   |
|  | <input type="checkbox"/> Authorized Generic                     |
|  | *If Authorized Generic, other section fields are not applicable |

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

| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION       |               |
|--|---------------|
| Does supplier meet DSCSA definition of manufacturer?     | Yes           |
| 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            |
| GLN:   | 0359746000004 |
| If Yes, was original product purchased direct from mfr?  |               |
| If yes, attach documentation from FDA.                   |               |

| ITEM AND PACKING INFORMATION     |             |                        |        |       |               |           |
|----------------------------------|-------------|------------------------|--------|-------|---------------|-----------|
| Item:                            | Weight Lbs. | Dimensions (US msmts.) |        |       | Volume (Cube) | # Pieces: |
|                                  |             | Depth                  | Height | Width |               |           |
| Box/ Carton/ Bundle/ Inner Pack: | 0.09        | 1.9                    | 4      | 1.9   | 14.44         | 1         |
| Case:                            | 2.8         | 11.5                   | 5      | 7.75  | 445.63        | 24        |
| Pallet:                          |             |                        |        |       | 0             |           |
| UPC:                             | Case:       |                        |        |       |               |           |
|                                  | Carton:     |                        |        |       |               |           |

| GTIN PRODUCT INFORMATION            |                                 |                                     |      |          |                |                   |
|-------------------------------------|---------------------------------|-------------------------------------|------|----------|----------------|-------------------|
| Serialized?                         | Level                           | Saleable Unit                       |      | Quantity | GTIN-14        | Items aggregated? |
|                                     |                                 | Item                                | Unit |          |                |                   |
| <input checked="" type="checkbox"/> | Box/ Carton/ Bundle/ Inner Pack | <input checked="" type="checkbox"/> | 2D   | 1        | 00359746337308 |                   |
| <input type="checkbox"/>            | Case                            | <input checked="" type="checkbox"/> | 2D   | 24       | 40359746337306 |                   |
| <input type="checkbox"/>            | Pallet                          | <input type="checkbox"/>            | 2D   |          |                |                   |
| <input type="checkbox"/>            |                                 | <input type="checkbox"/>            | 2D   |          |                |                   |
| <input type="checkbox"/>            |                                 | <input type="checkbox"/>            | 2D   |          |                |                   |
| <input type="checkbox"/>            |                                 | <input type="checkbox"/>            | 2D   |          |                |                   |
| <input type="checkbox"/>            |                                 | <input type="checkbox"/>            | 2D   |          |                |                   |
| <input type="checkbox"/>            |                                 | <input type="checkbox"/>            | 2D   |          |                |                   |
| <input type="checkbox"/>            |                                 | <input type="checkbox"/>            | 2D   |          |                |                   |

| COST INFORMATION                    |        | WHOLESALE USE ONLY: |  |
|-------------------------------------|--------|---------------------|--|
| Regular Cost                        |        | Vendor #:           |  |
| Invoice Cost (WAC) (\$)             | \$6.26 | Whsl. Code #:       |  |
| Federal Excise Tax Per Unit of Sale |        | Fineline Code:      |  |
| As of date:                         |        |                     |  |

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?<br>(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?<br>(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

- |  |   |
|--|---|
| <input type="checkbox"/> Organic<br><input type="checkbox"/> Inorganic<br><input type="checkbox"/> Steroid/Androgen<br><br><input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input style="width: 100px;" type="text"/> | <input type="checkbox"/> Corrosive<br><input type="checkbox"/> Oxidizer<br><input type="checkbox"/> Contact Hazard<br><br>Is the product a NIOSH hazardous drug? <span style="float: right;">No</span><br>If yes, indicate which: <input style="width: 100%; height: 20px;" type="text"/> |
|--|---|

### 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"/> |         |                          |                          |                          |             |   |        |                          |   |             |   |               |   |        |   |   |   |                          |  |               |   |       |  |        |  |   |
| 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"/>   |                          |   |   |         |                          |                          |                          |             |   |        |                          |   |             |   |               |   |        |   |   |   |                          |  |               |   |       |  |        |  |   |
| 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"/> |                          |  |               |   |       |  |        |  |   |
| <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"/>  |                          |   |   |         |                          |                          |                          |             |   |        |                          |   |             |   |               |   |        |   |   |   |                          |  |               |   |       |  |        |  |   |
| 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?<br/> <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"/>   |  |                          |   |   |         |                          |                          |                          |             |   |        |                          |   |             |   |               |   |        |   |   |   |                          |  |               |   |       |  |        |  |   |