



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: Final VersionDate:

| PRODUCT INFORMATION | |
|---|---|
| Company Name: | Jubilant Cadista Pharmaceuticals Inc. |
| 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: | 59746-0337-10 |
| Individual Unit NDC: | |
| UPC: | 3-59746-337-10-0 |
| UDI | |
| CVX Code: | |
| MVX Code: | |
| Description: | Losartan HCTZ 50-12.5mg Tablets 1000ct. |
| 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° I |
| 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? | <input type="text" value="Yes"/> |
| reverse numbered? | <input type="text" value="No"/> |
| co-licensed? | <input type="text" value="No"/> |
| Is the Product... Direct-Ship Only | <input type="text" value="Direct-Ship Only"/> |
| Is the Product... | <input type="text" value=""/> |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? | <input type="text" value=""/> |
| If Unit Dose NDC, indicate NDC here: | <input type="text" value=""/> |
| Country of Origin | <input type="text" value=""/> |
| Is this product covered under the Trade Agreements Act (TAA)? | <input type="text" value="Yes"/> |

| PRODUCT DESCRIPTION INFORMATION | |
|---------------------------------|------------------|
| Size: | 1000ct |
| 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 12 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 Power Multi | |
| <input type="checkbox"/> Other: Write In | |
| | Minimum order quantity? <input type="text" value="Yes"/> |
| | If Yes, how many of which package type? |
| | <input type="text" value="12"/> Each |
| | <input type="text" value=""/> |
| | <input type="text" value=""/> |
| | <input type="text" value=""/> |

| 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 |

| PHARMACY ORDER / BILL UNIT | |
|-------------------------------|-------------------------------|
| Rec. sell unit to customer? | Rx billing unit to pharmacy: |
| <input type="text" value=""/> | <input type="text" value=""/> |
| (Write-in, e.g. 1 Vial) | Each |
| | Gram |
| | Milliliter |

| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION | |
|--|--|
| Does supplier meet DSCSA definition of manufacturer? | <input type="text" value="Yes"/> |
| Is product exempt from DSCSA? | <input type="text" value="No"/> |
| If yes, select exemption: | <input type="text" value=""/> |
| Other exemption - Write in: | <input type="text" value=""/> |
| Is product repackaged? | <input type="text" value="No"/> |
| Is product sold by manufacturer's exclusive distributor? | <input type="text" value="No"/> |
| Has FDA granted waiver/exception/exemption for product? | <input type="text" value="No"/> |
| GLN: | <input type="text" value="0359746000004"/> |
| If Yes, was original product purchased direct from mfr? | <input type="text" value=""/> |
| 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: | 0.7 | 3.5 | 6.3 | 3.5 | 77.18 | 1 |
| Case: | 11.51 | 14.25 | 8 | 10.75 | 1225.5 | 12 |
| Pallet: | | | | | 0 | |
| UPC: | | | | | | |
| Case: | | | | | | |
| Carton: | | | | | | |

| GTIN PRODUCT INFORMATION | | | | | |
|-------------------------------------|------------------------------|-------------------------------------|------|----------|----------------|
| Serialized? | Level | Saleable Unit | | Quantity | GTIN-14 |
| | | Item | Unit | | |
| <input checked="" type="checkbox"/> | Box/Carton/Bundle/Inner Pack | <input checked="" type="checkbox"/> | 2D | 1 | 00359746337100 |
| <input type="checkbox"/> | Case | <input checked="" type="checkbox"/> | 2D | 12 | 40359746337108 |
| <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 | | |
| <input type="checkbox"/> | | <input type="checkbox"/> | 2D | | |

| COST INFORMATION | | WHOLESALE USE ONLY: | |
|-------------------------------------|----------|---------------------|--|
| Regular Cost | | Vendor #: | |
| Invoice Cost (WAC) (\$) | \$208.89 | 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? (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

- | | |
|---|--|
| <input type="checkbox"/> Organic <input type="checkbox"/> Inorganic <input type="checkbox"/> Steroid/Androgen | <input type="checkbox"/> Corrosive <input type="checkbox"/> Oxidizer <input type="checkbox"/> 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: 60%;">a. EDI</td> <td style="width: 10%; text-align: center;"><input type="checkbox"/> Yes</td> <td style="width: 30%;"></td> </tr> <tr> <td>b. Autofax</td> <td style="text-align: center;"><input type="checkbox"/> 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"/> 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>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>Site Address: <input style="width: 100%;" type="text"/></td> </tr> </table> <p>Minimum Order Quantity: <input style="width: 100%;" type="text" value="12"/></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: 100%;" 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: 100%;" type="text"/></p> <p>Ships for second day receipt: <input style="width: 100%;" type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input style="width: 100%;" 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: 100%;" type="text"/> | | | | | | | | | | | | | | | | | | | | | | |
| 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: 100%;" type="text"/></p> <p>Drop Ship service fee billed with each order: <input style="width: 100%;" type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input style="width: 100%;" type="text"/></p> <p>Comments: <input style="width: 100%; height: 80px;" type="text"/></p> | <p>Overnight receipt available: <input style="width: 100%;" type="text"/></p> <p>PO Receipt cut off time: <input style="width: 100%;" 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: 100%;" type="text"/></p> <p>PO Receipt Cut off time: <input style="width: 100%;" type="text"/></p> <p>Saturday Overnight receipt available: <input style="width: 100%;" type="text"/></p> <p>PO Receipt Cut off time: <input style="width: 100%;" 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: 30%;"><input style="width: 100%;" type="text"/></td> <td style="width: 40%;">Phone #:</td> <td><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 colspan="3"><input style="width: 100%;" type="text"/></td> </tr> </table> <p>Overnight Fees apply: <input style="width: 100%;" type="text"/></p> <p>Other fees apply: <input style="width: 100%;" 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: 100%;" type="text"/></p> <p>Restricted to retail pharmacy only: <input style="width: 100%;" type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input style="width: 100%;" type="text"/></p> <p>Restricted from US territories? (explain in comments) <input style="width: 100%;" type="text"/></p> <p>Comments: <input style="width: 100%; height: 80px;" 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: 100%;" 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: 100%;" 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: 100%;" type="text"/></p> <p>Is product order for restocking purposes? <input style="width: 100%;" type="text"/></p> | | | | | | | | | | | | | | | | | | | | | | |
| Miscellaneous Notes: | ADDITIONAL INFORMATION | | | | | | | | | | | | | | | | | | | | | | |
| <input style="width: 100%; height: 80px;" type="text"/> | <p>Is product order for scheduled patient procedure? <input style="width: 100%;" type="text"/></p> <p>Is product order for restocking purposes? <input style="width: 100%;" type="text"/></p> | | | | | | | | | | | | | | | | | | | | | | |