# HDA

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

**Version 2021**  **Introduction Type:** Post Launch Change  **x** Final Version  **Date:** 7/12/2021

## PRODUCT INFORMATION

| | |
|---|---|
| Company Name: | Jubilant Cadista Pharmaceuticals Inc. |
| Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): | 203536 |

**Application:** ANDA

Medical Device Class, if applicable:

DUNS: 022490515

Proprietary Name (If Applicable) and Established Name: Valsartan Tablets

| Selling Unit NDC: | 59746-362-90 | Unit of Use NDC: | | UPC: | 3-59746-362-90-4 |
|---|---|---|---|---|---|
| UDI | | CVX Code: | | MVX Code: | |

Description: Valsartan 160mg 90ct Tablet

Active Ingredient(s): Valsartan

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 | | | |

### ADDITIONAL PRODUCT INFORMATION

| | | | |
|---|---|---|---|
| The product is? | | Is the Product… | Direct-Ship Only |
| a legend device? | No | Is the Product… | Neither |
| if yes, enter class # | | Orphan Drug Status | |
| a product kit? | No | | |
| if yes, list NDCs of component parts | | FDA Approval Status | |
| reverse numbered? | No | | |
| co-licensed? | No | Allergens Present | |
| latex-free? | Yes | | |
| preservative-free? | No | | |
| correctional institution block? | Yes | | |
| opioid? | No | | |
| Cannabinoid? | No | Country of Origin | IN |

If Unit Dose, is item bar coded to unit dose for hospital scanning?

Is this product covered under the Trade Agreements Act (TAA)? No

If Unit Dose, indicate NDC here:

### PRODUCT DESCRIPTION INFORMATION

| | |
|---|---|
| Size: | 90 count |
| Strength: | 160mg |
| Dosage Form: | TABLET |
| Product Shape: | Oval, Biconvex |
| Product Color: | Yellow |
| Product Imprint: | C4 / C |

### FOR GENERIC DRUG PRODUCTS

Authorized Generic  *If Authorized Generic, other section fields are not applicable

| I. Orange Book Rating: | AB |
|---|---|
| II. Generic Equivalent to What Brand?: | Diovan |

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

| | | | |
|---|---|---|---|
| Does supplier meet DSCSA definition of manufacturer? | Yes | GLN: | 8902805000006 |
| Is product exempt from DSCSA? | No | | |
| If yes, select exemption: | | GCP: | 0359746 |
| 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 | | |
| Has FDA granted waiver/exception/exemption for product? | No | Provide source manufacturer for repackaged product | |
| If yes, attach documentation from FDA. | | | |

### GTIN AND HIBCC PRODUCT INFORMATION

| | Saleable Unit of Measure | Saleable Quantity | HIBCC | GTIN-14 | Unit of Use GTIN-14 |
|---|---|---|---|---|---|
| X | Item/Each | 1 | | 00359746362904 | |
| | Box/Carton/Bundle/Inner Pack | | | | |
| X | Case | 48 | | 40359746362902 | |
| | Pallet | | | | |

## 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)

Notes

| | |
|---|---|
| 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 Service |
|---|---|
| Number: | (800) 313-4623 |
| Group E-mail: | customer.service@cadista.com |

| 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: | 24 Months |
| Initial shelf life at launch (if different): | Months |

### ORDER INFORMATION

| | Unit of Sale | What is the NDC selling unit? |
|---|---|---|
| X | Bottle | 1 bottles of 90 tablets |
| | Box/Carton | (Write-in, e.g. 1 Box of 10 Vials) |
| | Ampule | |
| | Glass | Minimum order quantity? Yes |
| | Tube | |
| | Vial Liquid Sgl | |
| | Vial Liquid Multi | If Yes, how many of which package type? |
| | Vial Powder Sgl | 48 Each |
| | Vial Power Multi | Inner/Carton/Pack |
| | Other: Write In | Case |

### PHARMACY ORDER / BILL UNIT

| Rec. sell unit to customer? | Rx billing unit to pharmacy: | |
|---|---|---|
| 1 bottles of 90 tablets | x | Each |
| (Write-in, e.g. 1 Vial) | | Gram |
| | | Milliliter |

### ITEM AND PACKING INFORMATION

| | Weight Lbs. | Depth | Width | Height | Volume (Cube) | Saleable # Pieces |
|---|---|---|---|---|---|---|
| Item/Each: | 0.17 | 1.87 | 1.87 | 4.37 | 15.28 | 1 |
| Box/Carton/Bundle/Inner Pack: | | | | | 0.00 | |
| Case: | 10.9 | 15.63 | 11.89 | 6.1 | 1133.63 | 48 |
| Pallet: | | | | | 0.00 | |

*Dimensions (US msmts.)*

### COST INFORMATION

| | |
|---|---|
| Regular Cost | |
| Invoice Cost (WAC) ($) | $22.99 |
| As of date: | |

### WHOLESALER USE ONLY:

| | |
|---|---|
| Vendor #: | |
| Whsl. Code #: | |
| Fineline Code: | |

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:**

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

**Version 2021**                                    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? | No |
|     (If yes, attach SDS with special instructions.) | |
| e. Does the product contain DEHP? | No |

| | |
|---|---|
| Is this product regulated for shipment by DOT? | No |

(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? | No |

(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: | No |

- [ ] 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 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: | |

### 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 | | NCPDP#: | |
|     by Supplier: | | 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:

Release DATE

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

**Version 2021**   FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

## Order Method for Designated Drop Ship Product

Purchase orders may be accepted by:
- a. EDI
- b. Autofax    Fax Number:
- c. Fax    Fax Number:
- d. Phone only    Phone No.:
- e. Supplier Web Site only    Site Address:

Minimum Order Quantity:

Supplier's Customer Service Number:

Contracted 3PL company / contact #:    Name:
    Phone:

## Standard Order Receipt and Processing

**Purchase order daily receipt cut off time by supplier**

Cut off time:

Shipping lead time of PO:    Hours    Days

Ships same day for next day receipt:

Ships for second day receipt:

Ships regular ground for 3-10 days receipt:

## Expedited Freight Charges or Other Designated Drop Ship Fees:

Expedited freight fees billed with each order:

Drop Ship service fee billed with each order:

Drop Ship miscellaneous fees billed:

Comments:

## Overnight and Priority Overnight PO Processing

**Overnight receipt available:**

PO Receipt cut off time:

    Days of week overnight is available:    Monday
    Tuesday
    Wednesday
    Thursday
    Friday

**Priority Overnight receipt available:**
    PO Receipt Cut off time:

**Saturday Overnight receipt available:**
    PO Receipt Cut off time:

Order receipt method:    Phone:    Phone #:
    Fax:    Fax #:
    EDI:

Overnight Fees apply:

Other fees apply:

## Class of Trade Restriction:

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

Restricted to retail pharmacy only:

Restricted to hospital, clinics, and physician offices only:

Restricted from US territories? (explain in comments)

Comments:

## Other Data Information Required to Process PO:

Patient Procedure Date:

Physician Name:

Physician/Clinic Phone #

Physician State License #

Physician/Clinic DEA #:

Physician/Clinic Specialty:

## Return Instructions

Contact # if product is 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:

## ADDITIONAL INFORMATION

Is product order for scheduled patient procedure?

Is product order for restocking purposes?